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(54) Title: ASSESSMENT, PREVENTION AND TREATMENT OF ORAL DISEASE

(57) Abstract

A method of managing the dental health of a patient is provided. The method comprises the steps of assessing patient risk factors relevant to the development of caries and risk factors relevant to the development of periodontitis. A risk assessment level is determined incorporating a computerized model and a central database for collection of information. Treatment options are selected based on the risk assessment levels for that patient. The treatment options teach an ordered stepwise method of managing individual patient care based on patient need and prevention. Cost containment and cost efficiencies are significant.

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ASSESSMENT, PREVENTION AND TREATMENT OF ORAL DISEASE

FIELD OF THE INVENTION

This invention relates to the practice of dentistry, and more particularly to methods for reducing the risk of cariogenic disease and of periodontal disease in dental patients.

BACKGROUND OF THE INVENTION

Increasingly, dentists are required to provide more cost-effective services for both the insured and uninsured patient. Historically, the current models of dental care have either over-treated or under-treated the general population without focusing on identifying the particular needs and the expected needs of individual patients. Conventional fee-for-service dental plans designed in the 1970's no longer address the economic and clinical realities of the 1990's. These plans are no longer able to meaningfully contain costs or deliver oral health care/dental health care consistent with the concept of overall patient management and the inclusion of preventive measures to reduce the need for restorative therapy. The old modality of "drill, fill and scrape" is one approach but this approach acts only once the damage has occurred.

Not all patients are at risk of cariogenic disease (e.g. caries). Similarly, not all patients are at risk of periodontal disease (e.g. periodontitis). Effective medical management of dental caries and periodontal disease is required for those populations which exhibit increased risk factors for these conditions. Identification of the relevant risk factors and the subsequent identification of the relevant populations is an ongoing process that continues to be defined and redefined as scientific knowledge and understanding of these conditions improves. There is no known standardized approach for incorporating all risk factors, with appropriate weightings, into the treatment decisions.

It is now believed to be more appropriate to operate dental plans on a scientifically proven model of risk assessment and disease management. Increasingly, third party groups such as employers and insurers, and patients

not covered by dental insurance, are demanding preventive care based on more objective standards of risk assessment. A pressing need exists for object dental risk assessment protocols and preventive care procedures, and an effective method of making such protocols and procedures less expensive. There is also a pressing need for providing a means for ensuring that those protocols and procedures keep pace with dental research and associated new technologies and products so that the most effective tools are always available to dental practitioners.

The process of assessing risk of dental disease, individualizing care, individualizing patient coverage based on need, and educating patients about their own dental needs and care is a complex process. Patients who consistently demonstrate that they are at low risk of caries and periodontitis do not need the same treatment or management as those who are evaluated to be at risk. However, a system needs to be in place to determine with consistency and sound predictability who is at risk and who is not. The development of a risk assessment model that can be individualized for a particular patient goes beyond the scope of current patient models of treatment, management and coverage.

There is an ongoing need for methods of risk assessment and oral health disease management that provide a means by which development of dental disease can be prevented or at least reduced. Provision to the dental profession of objective test protocols geared to the unique needs of the individual patient would clearly represent a more efficient way to provide dental treatment.

SUMMARY OF THE INVENTION

Accordingly, in one aspect of the present invention, a kit is provided for determining an individual's risk of oral disease and for selecting a treatment option, such a kit comprising:

a) a risk questionnaire to be completed by an individual and the individual's dentist for assessing an individual's risk factors relevant to oral disease;

b) a computer system for calculating a risk assessment level based on the risk factors assessed using the questionnaire;

c) a treatment kit for use in a treatment option which is selected based on the risk assessment level.

In another aspect of the present invention, there is provided a method for providing an index for assessing oral disease comprising the steps of;

a) assessing risk factors' relevant to oral disease;

b) calculating a risk assessment level based on the risk factors of step (a); and

c) indexing the risk assessment level with treatment options.

Another aspect of the present invention provides a method of assessing the risk of dental disease comprising the steps of evaluating parameters of a patient indicative of respective risk factors, weighting the risk factors, combining the weighted risk factors to produce an overall risk assessment value and selecting a treatment option on dependence thereon and in accordance with predetermined criteria.

In another aspect of the present invention, the use of a fluoride in the manufacture of a medicament for the treatment or prevention of oral disease is provided, wherein the medicament is used in a method of assessing dental health comprising;

a) assessing risk factors relevant to oral disease;

b) calculating a risk assessment level on the risk factors of step (a); and

c) selecting and initiating a treatment option comprising the use of the medicament based on the risk assessment level.

In yet another aspect of the present invention, the use of an antibiotic in the manufacture of a medicament for the treatment or prevention of oral disease is provided, wherein the medicament is used in a method of assessing dental health comprising;

a) assessing risk factors relevant to oral disease;

b) calculating a risk assessment level on the risk factors of step (a); and

c) selecting and initiating a treatment option comprising the use of the medicament based on the risk assessment level.

The kit and methods of the present invention are comprehensive in both their assessment of risk and in their formulations of treatment methods or regimens. The present invention takes into account risk factors for caries and risk factors for periodontal disease, and takes into account adjustments in the treatment method for a patient according to a substantially objectively defined risk level. For these reasons, the kit and methods of the present invention are more sophisticated than existing protocols and treatment is further differentiated according to actual patient need rather than existing treatments for dental patients. For example, specific treatment options are provided by which the patient's treatment can be adjusted when their dental health for cariogenic or periodontal disease either improves or worsens.

The algorithms, weighting and scoring used in establishing the kit and methods of the present invention are new as is the identification of a standardized methodology for treatment options. It is recognized that modifications to the algorithms for weighting and scoring the various risk factors will occur over time as knowledge of these conditions improves. The advantages of such a system are clearly cost containment, ease of prediction and prevention of disease. Moreover, a model which improves on existing treatment methodologies and goes beyond the dental tradition of restoration after disease has already taken its toll is provided.

The kit and methods of the present invention provide a systematic approach which can facilitate scientific advancements in the field of oral health. Accordingly, the weightings and scorings can be adjusted from time to time as more knowledge is gained about the true nature of the risk associated with cariogenic and periodontal disease.

Embodiments of the present invention will be further described by reference to the following figures, charts, tables and forms, in which:

BRIEF DESCRIPTION OF THE TABLES, FIGURES, CHARTS AND FORMS

Figure 1 is a table of dental risk factors, weighting factors and scoring for assessing a patient's susceptibility to dental caries;

Figure 2 is a table showing the dental risk factors, weighting factors and scoring for assessing a patient's susceptibility to periodontal disease;

Figure 3 is a schematic diagram of a preferred embodiment of a computerized system in accordance with the invention;

Figures 4A and 4B are flow diagrams showing an overview of the principal functions of the web server of Fig. 3;

Chart 1 is a chart outlining the preferred protocol for patients at moderate risk with early adult periodontitis;

Chart 2 is a chart outlining the preferred protocol for patients at high risk of limited adult periodontitis;

Chart 3 is a chart outlining the preferred protocol for patients at high risk of extensive adult periodontitis;

Form 1 is an example of the type of questionnaire that a patient and dental care provider may complete to collect the information necessary for the dental risk assessment; and

Form 2 is a sample of the type of form that can be automatically generated and provided to the patient to keep them informed about one or more aspects of their treatment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A kit useful in determining a treatment option based on an individual's risk factors with respect to oral disease is provided. The kit incorporates a questionnaire for completion by the individual and the individual's dentist which, once completed, provides the information required to determine the risk factors of the individual that are associated with oral disease. The risk factors are used in a computer system to calculate a risk assessment level which determines the selection of a treatment option from a treatment kit. The kit may additionally include a bacterial assessment kit for determining

cariogenic bacteria or periodontal pathogens in an individual's oral cavity when the risk assessment level indicates the patient to be at risk.

Upon visiting their dentist, patients complete a questionnaire (for example such as is found in Form 1) which, coupled with a dental exam, facilitates the completion of a Dental Risk Assessment in connection with caries and periodontitis. The dentist completes the section of the form relating to the dental examination. The Dental Risk Assessment of the present invention is an Assessment of risks, patient health and other factors known to relate to oral health management of caries and periodontitis in a patient. At the end of a Dental Risk Assessment in accordance with the present invention a patient is assigned a risk level for cariogenic disease and a risk level for periodontal disease. The risk category assigned to the patient will determine whether the patient must undergo a Bacterial Risk Assessment in which the patient is tested for the presence and/or level of certain bacteria in the oral cavity.

BACTERIAL RISK ASSESSMENT

There are two types of Bacterial Risk Assessments that are integral to the kit and methods of the present invention. The first is a caries bacterial risk assessment and the second is a periodontal bacterial risk assessment. The caries bacterial risk assessment comprises two components: testing for cariogenic bacteria and radiographic procedures. The periodontal bacterial assessment comprises three components: testing for periodontal pathogens, charting of diseased pockets and radiographic procedures.

Researchers have identified the role of certain anaerobic bacteria in the emergence and progression of adult periodontitis: *Porphyromonas gingivalis*, *Bacteroides forsythus* and *Treponema denticola*. The titer and relative proportion of these specific organisms in subgingival plaque have been correlated with the common forms of adult periodontitis in several clinical studies.

Scientific studies have shown that the presence of these bacteria in the periodontal pocket have been associated with:

- significantly greater attachment loss over time, compared to pockets without these bacteria
- bleeding on probing of the sample site
- future risk of disease and recurrence of the disease
- the potential for intra-family periodontal problems -- children whose parents had clinical evidence of periodontitis (and who also had high levels of these bacteria) were substantially more likely to be colonized by these same microorganisms.

To determine the patient's risk level for caries and for periodontitis, risk factors are identified and incorporated into an overall risk level assessment. Individually, particular risk factors are known by those skilled in the art in accordance with current literature in the art. These factors are used as indicators in the risk assessment of each patient. The selection of the pertinent factors will change with time as knowledge of the nature of these diseases and their progression increases.

A Bacterial Risk Assessment is triggered when certain events occur. The computerized system which forms part of the kit of the present invention and is used in the methods of the present invention will identify when either a caries or periodontal bacterial risk assessment is required. The presence of certain factors will automatically trigger a Caries Bacterial Risk Assessment. These include the presence of active caries, the use of xerostomic medications by the patient, the presence of orthodontic appliances and radiation about the head/neck area, for example as part of a cancer therapy program.

A Caries Bacterial Risk Assessment can also be triggered when the sum total of all caries risk factors reach or exceed a certain pre-determined threshold. A computerized system for calculating a risk assessment level can be programmed based on the latest scientific knowledge to include current factors known to impact on the development and/or prevention of caries. Similarly the computerized system can be programmed to weight the various factors based on current knowledge in the field.

The presence of certain factors will also automatically trigger a Periodontal Bacterial Risk Assessment. These factors include mobility of the teeth or bleeding/inflamed gums then a Periodontal Bacterial Risk Assessment is triggered. Like the caries testing, a Periodontal Bacterial Risk Assessment can also be triggered when the sum total of all periodontal risk factors reach or exceed a certain pre-determined threshold. A computerized system for calculating a risk [illegible] level can be programmed based on the latest scientific knowled[illegible] current factors known to impact on the development and/or pre[illegible]eriodontitis. Similarly the computerized system can be programmed to [illegible]t the various factors based on current knowledge in the field.

The results of the Dental Risk Assessment coupled with the results of the Bacterial Risk Assessment (if needed) drive the treatment decisions for that patient. Both of these Assessments are described in greater detail below.

The results of the Dental Risk Assessment determine the patient's risk of caries and/or periodontal disease. Risk Levels for caries and periodontal disease are determined individually. Active caries, xerostomic medications, orthodontic appliances, radiation about the head/neck, or a predetermined threshold based on a total of all caries risk factors will all trigger a Caries Bacterial Risk Assessment (e.g. testing for cariogenic bacteria and radiographic procedures). On the other hand, mobility (i.e. the tendency of a tooth to be displaced), bleeding/inflamed gums, or the sum total of all periodontal risk factors above a predetermined threshold will trigger a Periodontal Bacterial Risk Assessment (e.g. testing for periodontal pathogens, charting of diseased pockets and radiographic procedures).
A trigger for both Caries and Periodontal Bacterial Risk Assessments will be high and frequent spending on Restorative and/or Periodontal care.

Dental Risk Assessment is included as part of the new patient examination. For recall patients, Dental Risk Assessment is a separate procedure. Children under the age of seven are not risk assessed and for children older than seven years of age active decay on primary teeth will not

be considered in the risk assessment for that patient. The frequency of recall examinations is related to the risk category for both caries and periodontal disease. Patients assessed at low risk for both caries and periodontitis are usually seen at the rate of one recall visit per year. Patients assessed at risk for caries or periodontitis are scheduled for two recall appointments per year.

If a patient is assessed to be at risk of cariogenic disease on the basis of a Dental Risk Assessment then a Caries Bacterial Risk Assessment is performed to determine the level of *Streptococcus mutans* in the patient's oral cavity. An example of one such test is the CarieScreen™ test for which test results are available in 48 hours. The results from the *Streptococcus mutans* test will indicate the concentration of *Streptococcus mutans* in the saliva as measured in colony forming units per millilitre of saliva (cfu/ml).

Other suitable testing means for *Streptococcus mutans* would be known to persons skilled in the art. For example, Canadian Patent No. 1,235,986, which issued May 3, 1988 to Jordan and Marmel, discloses a test kit and method for the determination of *Streptococcus mutans* in the oral cavity of a dental patient. The test is a semi-quantitative determination which is suitable for use by dentists and dental professionals in a non-laboratory environment. The test kit is sold commercially under the trade-mark CARIESCREEN SM by APO Diagnostics Inc. of Markham, Ontario, Canada. The test is an in vitro semi-quantitative dip-slide culture test for the detection of *Streptococcus mutans* in the oral cavity by use of a selective culture medium.

The results of the Bacterial Risk Assessment determine the selection of the patient's treatment plan for treatment and management of caries. There are three possible treatment plans: Caries Risk/Low Bacteria, Caries Risk/Medium Bacteria and Caries Risk/High Bacteria Treatment Plans. In this regard, antimicrobial treatment is preferred to antibiotic treatment since the antimicrobial may be given for a long period of time without the risk of developing resistant strains as is the case with antibiotics.

Objective measurements of levels of *Streptococcus mutans* can be used as an indicator of an individual's likelihood of developing dental caries in the future as well as control of existing dental caries. Furthermore, it is recognized as an aspect of the present invention, that the change in the concentration of *Streptococcus mutans* in the oral cavity in response to a first treatment with an antimicrobial and a second treatment with a fluoride could be predictive of a patient's future risk of dental caries.

If a patient is assessed to be at risk of periodontal disease on the basis of a Dental Risk Assessment then a Periodontal Bacterial Risk Assessment is done to test for anaerobic periodontal pathogens. Pocket depths are charted for diseased sites. The results of the Bacterial Risk Assessment with pocket depths, determine the patient's Preventive Treatment Plan for periodontal disease.

Testing for the presence of bacterial periodontal pathogens can be performed in any manner which would be known to a person skilled in the art. In preferred embodiments of the invention, testing is directed towards anaerobic periodontal pathogens, many of which can be identified using an enzymatic test wherein the hydrolysis of benzoyl-DL-arginine-naphthylamide is detected. In a specific embodiment, the testing for one of three specific periodontal pathogens is performed using a test kit sold by Knowell Periodontal Technologies, Inc. under the trade mark Bana™. However, there are certain rare instances in which a periodontal pathogen would not be identified by such an enzymatic test. In those instances, the presence of periodontal pathogens must be determined using other methodologies known to persons skilled in the art.

If the test results are negative for periodontal pathogen then the dentist is quickly alerted to the fact that any clinical symptoms observed (such as bleeding and pocket depth) are not caused by the presence of periodontal pathogen(s). At that point in time the dentist is alerted to a possible need to change the treatment approach.

It is recognized that many presentations of adult periodontitis can be managed by the general practitioner; however, there are numerous situations which require a periodontal specialist once an active periodontal infection has been detected. These situations include, but are not limited to, the following:

- I. refractory or recurrent periodontitis
- ·. moderately severe to severe periodontal disease
- ·. after antimicrobial and scaling therapies where deep pockets with bleeding remain with or without a positive bacteriologic test for anaerobic periodontal pathogens
- ·. when regenerative therapy is being considered for either hard or soft tissues.

U.S. Patent Application Serial Number 08/476,197, entitled METHOD FOR THE DIAGNOSIS AND REDUCTION OF PERIODONTITIS and filed on June 7, 1995, describes certain methods for the diagnosis, treatment and reduction of periodontitis and teaches in detail the state of the art relating to prevention and management of periodontal disease at the time of filing that application.

Canadian Patent Application Serial Number 2,166,646, entitled CARIES TREATMENT METHOD WITH FLUORIDE, filed on January 5, 1996 and due to be laid open July 6, 1997, describes certain methods for the diagnosis, treatment and reduction of caries and teaches in detail aspects relating to the diagnosis, treatment and prevention of cariogenic disease at the time of filing that application.

One of the several preventive treatment options, based on the patient's assessed risk for caries and for periodontal disease, is selected. Each treatment option has its own time line as detailed below.

LOW RISK PREVENTIVE TREATMENT OPTION
(CARIES AND PERIODONTITIS BOTH LOW)

On Day 1 a new patient examination or recall examination is initiated and a Dental Risk Assessment is made. The Dental Risk Assessment factors as determined by the examination and by completion of a questionnaire, e.g.

Form 1, are entered into a computer system, preferably comprising a proprietary database, and a proprietary software analysis is performed based on all of the criteria entered into the system. Typically, dental information is collected at a central processor and a risk determination for caries and for periodontal disease is made by way of computer analysis. If there is no on-line access, for example through the internet, all data can be mailed to the central processor for subsequent data entry.

The risk factors relevant to cariogenic disease and to periodontal disease are weighted and a final risk assessment level is made for both aspects. If the analysis determines that the patient is at low risk for caries *and* at low risk for periodontal disease then the patient is scheduled to return in twelve months for re-assessment. Once it is determined that the patient is at low risk for both conditions the dentist will often proceed with other routine steps such as scaling, polishing and radiographs (if needed).

CARIES RISK/LOW BACTERIA PREVENTIVE TREATMENT OPTION

On Day 1 of a new patient examination or a recall examination a Dental Risk Assessment determines that the patient is at risk of caries. Once it has been determined that the patient is at risk of caries then a Bacterial Risk Assessment is initiated with a saliva test for *Streptococcus mutans*. Radiographs are taken. Open decay is restored and pit and fissure sealants are applied, if indicated. Scaling and polishing may also be done at this time.

At Day 3 - 10 a Bacteria Risk Assessment is done to determine the *Streptococcus mutans* levels. If the level is judged to be low, i.e. less than 250,000 cfu/ml then this patient is determined to be at caries risk with low bacteria count. Nonetheless, the patient is at risk of caries and, therefore, the Caries Risk/Low Bacteria Preventive Treatment Plan is initiated.

The Caries Risk/Low Bacteria Treatment Plan requires the topical application of fluoride varnish followed by two month follow-up home care fluoride program. Preferred home care fluoride treatment regimens of the present invention incorporate both fluoride gel (stannous fluoride) and fluoride

rinse (sodium fluoride) treatment regimens. In a preferred embodiment, the product FLUORZOINÔ is used as the source of fluoride for the fluoride regimen. Table 3, below, outlines preferred embodiments for a course of treatment incorporating the FLUORZOINÔ home care pack. The home care pack contains two 227 mL bottles of FLUORZOINÔ oral rinse containing 0.023% fluoride ion from 0.05% sodium fluoride and one 60 mL squeeze bottle of FLUORZOINÔ gel containing 0.4% stannous fluoride and one new toothbrush. One home care pack should last for 60 days of usage.

Other suitable concentrations and combinations of fluoride would be understood to be useful by a person skilled in the art who has had the benefit of the present disclosure. Factors to be considered when selecting an appropriate fluoride source, type and dosage are patient compliance, taste, potential for staining of teeth as well therapeutically acceptable thresholds for the person's age, weight and medical status. While fluoride oral rinsing (and home gel use) are safe from the medical standpoint, they are not recommended for children under 7 years of age because there is a significant risk that the entire dose could be consistently swallowed, thereby increasing the risk of enamel fluorosis.

A first recall visit is scheduled at Month 6 and at that recall visit a Dental Risk Assessment is repeated. If, at this point, it is determined that the patient is at low risk of caries then the patient is moved to the Low Risk Treatment Option (described above). If, on the other hand, the Dental Risk Assessment determines the patient to be "at risk" of caries then the Bacterial Risk Assessment is repeated and if the *Streptococcus mutans* level is judged "low" then the patient would remain in this category. Topical fluoride would be applied again and a further two month home care fluoride treatment home care program implemented.

It is important to note that this patient risk level is characterized as transitional, as the patient is either moving to Low Risk or emerging into Risk of Caries with Medium/High Bacteria.

CARIES RISK/MEDIUM BACTERIA PREVENTIVE TREATMENT OPTION

At Day 1 there is a new patient examination or a recall examination. A Dental Risk Assessment is performed which determines that the patient is at risk of caries. Once it is determined that the patient is at risk of caries, a Bacterial Risk Assessment is initiated with a saliva test for *Streptococcus mutans*. Where necessary, radiographs are taken and pits and fissure sealants applied, if indicated. Other routine matters would typically be addressed including the restoration of any open decay, scaling and polishing.

At Day 3 - 10 the results of the Bacterial Risk Assessment evidence a *Streptococcus mutans* level in the patient to be medium, i.e. (250,000 - 500,000 cfu/ml). A determination of medium levels of *Streptococcus mutans* puts the patient into the category "Caries Risk/Medium Bacteria" and the treatment option is initiated.

The Caries Risk/Medium Bacteria Treatment Plan continues at Day 3 - 10 with the application of a topical fluoride foam and a topical antimicrobial. The patient is dispensed a two month program of home care fluoride treatments.

The Caries Risk/Medium Bacteria Treatment continues with recall appointments scheduled at Month 6, Month 12 and Month 18. The protocol at Month 6 and Month 12 is the same. At each of Month 6 and Month 12 recall appointments, a Dental Risk Assessment and a Recall Examination are done. The results are entered into the computer system. The patient receives one application of Topical Foam and one application of Topical Antimicrobial. The patient continues on a home care fluoride treatment program for the following two month period. Scaling would also be done at this time.

A redetermination of the patient's risk level is made at Month 18 by way of a Dental Risk Assessment and Recall Examination. All factors are entered into the computer database and a determination is made of the patient's current risk level. If the patient is assessed to be at Low Risk of caries then the patient is placed on the Low Risk Treatment Option. If it is determined that

the patient continues to be "at risk" then a Bacterial Risk Assessment is taken. If the results of the Bacterial Risk Assessment show that the bacterial level is less 250,000 cfu/ml, the patient is moved down to the Caries Risk/Low Bacteria Treatment Option. If the results of the Bacterial Risk Assessment show that the patient's bacterial level is between 250,000 and 500,000 cfu/ml, the patient remains in the Caries Risk/Medium Bacteria Treatment Option. Patients who remain at this level have their risk level monitored every six months. An adjustment in treatment is made based on the Dental and Bacterial Risk Assessments which are made at these semi-annual appointments. Once the patient is determined to be at Low Risk then the 6 month recall appointments stop and the patient then follows the Low Risk Treatment Option.

If the bacterial level is assessed at greater than 500,000 cfu/ml, then the patient is moved up to the Caries Risk/High Bacteria Treatment Option detailed below.

Clinical factors used when deciding whether a patient is at medium to high risk of caries include:

- recurrent or residual decay, as shown by their treatment history;
- patients who are about to receive orthodontic care (as it is known that orthodontic appliances and/or brackets are natural sites for colonization of *Streptococcus mutans*;
- patients with crown and bridge restorations;
- patients with limited salivary flow (xerostomia) for example due to systemic medication (e.g. anti-hypertensives, anti-depressants, tranquilizers, antihistamines, and other drugs known to reduce saliva flow), systemic disease (e.g. Sjogren's Syndrome, scleroderma, lupus, rheumatoid arthritis), or with neurological conditions (e.g. Parkinson's Disease);
- new patients exhibiting poor oral hygiene, poor dental knowledge and/or poor compliance;
- patients under periodontal care with exposed root surfaces

- young mothers who have children between the ages of 2 and 3 (without treatment the mothers could readily transmit the infection to their children since children are not colonized by *Streptococcus mutans* at birth, only later by cross-infection)
- patients at peak periods for decay — in their early teens, 20's and over 55 years of age.

CARIES RISK/HIGH BACTERIA TREATMENT OPTION

At Day 1 of the Caries Risk/High Bacteria Treatment Option the patient is seen for examination either as a new patient or as a recall patient. A Dental Risk Assessment is done and it is determined that this patent is "at risk" of caries. Once it has been determined that the patient is at risk of caries, a Bacterial Risk Assessment is performed testing the saliva of the patient for *Streptococcus mutans*. If necessary, radiographs are taken. Pit and fissure sealants are applied, if indicated, and where appropriate open decay is restored. Scaling and polishing would also be done on Day 1 after the other procedures have been completed if warranted in the patient.

At Day 3-10 the patient returns for an appointment to learn of the results of the Bacterial Risk Assessment. The patient is grouped into the Caries Risk/High Bacteria Treatment Option when the Bacterial Risk Assessment determines that the *Streptococcus mutans* levels are high (i.e. greater than 500,000 cfu/ml). If the patient falls within this treatment group they received two treatments at Day 3- 10. A topical fluoride foam is applied and a topical antimicrobial is applied.

The patient returns for another appointment at Week 2. At this time a topical fluoride foam is applied again as is another topical antimicrobial.

At Week 3, the patient returns for another application of topical fluoride and another application of topical antimicrobial. At this time a 4 month supply of home care fluoride is dispensed to the patient for home use over the following four months.

At Week 4, the patient returns for another Bacterial Risk Assessment test. If the *Streptococcus mutans* levels revealed by the Bacterial Risk

Assessment are still greater than 500,000 cfu/ml, a fourth topical antimicrobial treatment is applied. It is also recommended that a specific patient status check (e.g. for interproximal decay) be performed at this time.

At Month 6, there is a recall examination and another Dental Risk Assessment is performed. A topical fluoride foam is applied at this time as is a topical antimicrobial. Another 4 month supply of home care fluoride is dispensed to the patient for home use over the following four months. Scaling may be recommended at this stage and could be done by the dentist at Month 6.

At Month 12 and at Month 18 the same steps are taken as described for Month 6.

At Month 24, there is a recall examination and a Dental Risk Assessment to determine risk level. If assessed at Low Risk of caries, then the patient moves into the Low Risk Preventative Treatment Option. Scaling and polishing may also occur at this time. If the patient is assessed as being "at risk" for caries then another Bacterial Risk Assessment is performed, for example on a sample of patient saliva. If the *Streptococcus mutans* level is less than 250,000 cfu/ml, the patient is moved down to the caries risk/low bacteria treatment option. If the *Streptococcus mutans* level is in the range between 250,000 to 500,000 cfu/ml then the patient is moved down to the caries risk/medium bacteria preventive treatment option. If the Streptococcus mutans level is greater than 500,000 cfu/ml, then the patient remains in the caries risk/high bacteria treatment option.

At Month 24, if the patient is still "at risk" for caries, the patient is monitored at 6 month intervals thereafter until the patient's Dental Risk Assessment is determined to be Low Risk. At the semi-annual recall appointments, based on the results of the Bacteria Risk Assessment, the patient may be adjusted to another treatment option until the patient is assessed to be at Low Risk.

Antimicrobials and fluoride are likely complementary in that they affect the opposite phases of the demineralization-remineralization cycle of the

tooth surface. Chlorhexidine (for example as sold under the brand name CHLORZOINÔ) controls the demineralization cycle of the tooth surface by directly controlling the plaque and the plaque's production of the acids. Ultimately this can influence the overall pH of the oral cavity or regions of the oral cavity. Fluorides (for example, the fluoride product sold under the brand name FLUORZOINÔ), on the other hand, encourage remineralization. The use of the two together achieves an effect that is not achieved by each alone as the antimicrobial has the effect of preparing the environment so it can optimize the benefits of the fluoride treatment.

The significant advantage of one of the preferred embodiments of the present invention is that the antimicrobial treatment is applied by the dentist and when incorporated into the methods of the present invention, significantly increases patient compliance and effectiveness of the treatment protocols.

In preferred embodiments of the present invention the antibiotic chlorhexidine is applied by the dentist in a relatively high concentration (as compared to the concentration in oral rinses or gels). In a preferred embodiment the concentration ranges from about 10% to about 20%. In a more preferred embodiment the concentration is about 10%, as applied by the dentist. The chlorhexidene continues to be released into the oral cavity for about 8 hours and sometimes longer. Surprisingly, this sustained release enhances the antimicrobial effect of the chlorhexidine without causing the common adverse effects of staining, loss of taste acuity and poor patient compliance. It may also be the case that the chlorhexidene is absorbed into the enamel of the tooth where it continues to have an effect. The preferred embodiments of the present invention integrate fluoride treatments into this process to obtain improved protection against dental caries and/or improved treatment of dental caries.

ASSESSING RISKS FOR ADULT PERIODONTITIS

At Day 1, a Dental Risk Assessment is performed to determine the patient's risk of periodontal disease. If it is determined that the patient is "at risk" of periodontal disease, a Bacterial Risk Assessment is initiated with a

microbiological test for an anaerobic infection. Probing depths are completely assessed and scaling is begun.

If the microbiological test is negative, it is not an anaerobic infection. The patient should be referred to a specialist as other forms of bacteria could be responsible, or a systemic disease could be responsible for producing the symptoms.

If the microbiological test is positive and the overall risk is moderate, then follow the Moderate Risk Early Adult Periodontitis Treatment Option as described below. Chart 1 sets out preferred embodiments. The patient can, using the computerized system, be picked up at any stage when they attend for their next appointment.

If the microbiological test is positive, and the overall risk is high, then follow the High Risk Limited or High Risk Extensive Adult Periodontitis Treatment Plan as described below. Charts 2 and 3 set out preferred embodiments.

ADULT PERIODONTAL RISK - MODERATE TREATMENT OPTION

On Day 1 the new patient or recall patient attends for the first appointment. A Dental Risk Assessment for the patient is used to make a determination of the patient's risk of adult periodontitis. If the patient is found to be "at risk" of adult periodontitis then a Microbiological Assessment for anaerobic periodontal pathogens is performed. The charting of pockets greater than 2 mm is documented and, if needed, radiographs are taken. If the anaerobic periodontal pathogens test is positive then scaling is begun on all pockets greater than 2 mm. More than one appointment for the scaling may be required.

If the patient is determined to be "at risk" of adult periodontitis but the test for anaerobic periodontal pathogens is "negative" the patient may be referred to a specialist.

On Day 10 - 30 the patient attends for a second appointment. Once scaling is completed in the infected areas, the area is retested for the presence of anaerobic periodontal pathogens. A positive test for anaerobic periodontal

pathogens must be accompanied by clinical signs and symptoms such as bleeding and/or inflammation. If the test is negative for anaerobic periodontal pathogens but there are clinical signs and symptoms of periodontal disease then the patient may be referred to a specialist for further assessment.

If, upon retesting, the test is negative for anaerobic periodontal pathogens and the gums and/or pockets are healing, then the patient goes into the maintenance phase of the treatment option with a six month recall visit.

If, upon retesting, the test is positive for anaerobic periodontal pathogens with continuing clinical signs and symptoms of disease, then the patient is rescaled. There may be additional appointments required for scaling to complete this second scaling.

If the patient undergoes the second scaling (because upon retesting they were positive for anaerobic periodontal pathogens) then they will return for a third appointment. The third appointment is scheduled for 10 to 30 days after the second appointment and the patient is again retested for the presence of anaerobic periodontal pathogens. If the patient now tests negative for anaerobic periodontal pathogens and the gums/pockets are healing then the patient is scheduled for a six month recall visit and assessment. On the other hand, if the patient still has clinical signs and symptoms of periodontal disease and the test is positive for anaerobic periodontal pathogens then treatment with either metronidazole or doxycycline is indicated, depending on the patient profile.

In another embodiment, the use of antibiotics may occur at the second appointment/second scaling stage.

If the patient is treated with antibiotics, then the patient should be retested for anaerobic pathogens after the course of antibiotics has been completed to monitor the efficacy and/or effect of the drug. Therefore, the patient will return for a fourth appointment about 10 to 30 days later. If the patient tests negative for anaerobic periodontal pathogens and there is evidence of gum/pocket healing then the patient is put into the maintenance phase and scheduled for a six month recall visit and assessment.

If, on the other hand, the patient tests positive for anaerobic periodontal pathogens with continuing clinical signs and symptoms of disease, then the patient may be referred to a specialist for further assessment. If the treating dentist is of the opinion that a second course of antibiotics would further improve the clinical condition, or improve a possible compliance problem, then a second course of antibiotics may be warranted. If the patient fails to respond clinically to the second course of antibiotics then they may be referred to a specialist for further assessment.

The stage in the treatment methodology is the First Recall Visit at six months. This is the Maintenance Phase. A recall examination is performed and a Dental Risk Assessment for periodontal disease is done to determine the patient's current risk profile. A Microbiological Assessment may be triggered for anaerobic periodontal pathogens, depending on the outcome of the Dental Risk Assessment. Pocket depths of greater than 2 mm are charted and scaling and polishing is completed. A second recall visit is then scheduled for similar treatment at a further 6 month interval. If the patient remains low risk for one full year, then that patient is moved into the low risk recall treatment option. If the patient develops clinical signs and symptoms, then the patient is moved into a periodontal preventive program.

ADULT PERIODONTAL RISK - HIGH/LIMITED & HIGH/EXTENSIVE TREATMENT METHODS

These two periodontal treatment options are used when the patient is assessed to be at high risk of periodontal disease. The treatment methodologies are similar to the steps outlined above for the Moderate Treatment Method with the exception that the patient is started on a course of antibiotics as soon as they reach the stage of the second scaling. There is therefore only a three appointment schedule for patients grouped as High Periodontal Risk. At any time when a patient tests negative for anaerobic periodontal pathogens and there is evidence of periodontal healing of the gums/pockets then the patient is moved into the low risk recall schedule with two six-month recall visits for reassessment.

Treatment of inflamed, positive sites with short-term, systemic antibiotics involves metronidazole or doxycycline over a period of 7 to 10 days respectively. Patients receiving this treatment should also be re-tested 10 to 30 days after treatment to ensure that this medication had the desired effect and to check on patient compliance to drug dosing. Weight guidelines for systemic antibiotics are set out in the following Table.

Weight Guidelines for Dispensing Antibiotics for Adult Periodontitis

patient's weight (pounds)	cumulative daily dose of metronidazole	cumulative daily dose of doxycycline
90 - 125 pounds	750 mg	100 mg
126 - 200 pounds	1.00 g	100 mg
200+ pounds	1.25 g	200mg first day followed by 100 mg/day thereafter

Given the diagnosis of an anaerobic infection in diseased pockets, the preferred antibiotic is metronidazole because of its spectrum of activity against anaerobes and because of its clinical safety and efficacy.

Patients who are social drinkers will generally have difficulty with the metronidazole medication if they imbibe while taking it since metronidazole can have an antabuse effect. Clinicians should query the patient about their use of alcohol during treatment, and , if any drinking is suspected, doxycycline at 100mg/day over 10 days, should be dispensed. Those patients receiving doxycycline should also be advised about taking this medication on a full stomach and without any calcium-containing (dairy) food products. Patients on doxycycline should also refrain from sun-bathing and those patients on birth control pills should be advised that all tetracycline products may interfere with the absorption of these pills. If there is no evidence of periodontal pathogens being present at the sites then the dentist is alerted to the fact that other causes are at play. Therefore, the dentist will not continue using costly

treatments and review the patient's overall treatment plan.

All of these methods take place in the offices of the general practitioner dentist's office. It is normally not necessary to have a referral to a periodontal specialist. In some instances, however, it may be necessary to refer to a periodontal specialist when the patient presents with severe clinical signs and symptoms of periodontal disease including Localized Juvenile Periodontitis (LJP). A referral is usually warranted when there are signs and symptoms of periodontal disease but tests for anaerobic periodontal pathogens are negative. Finally, a patient may be referred to a periodontal specialist if microbiological testing continues to give positive results for anaerobic periodontal pathogens when the patient has completed one or two courses of antibiotic therapy and is not improving clinically.

All of the treatment option methodologies described above are examples of preferred embodiments of the present invention and it is clear that modifications can be made within the scope of the invention as claimed.

SCORING AND WEIGHTING OF RISK FACTORS

The present invention provides a unique system of weighting risk factors/indicators for caries and for periodontitis, arriving at a score for each of the factors and then combining the scores to arrive at a final determination of either caries or periodontitis risk for the patient. The following risk factors are examples of contributing risk factors in the development of cariogenic disease: 1) presence of active caries, 2) the number of decayed, missing and filled teeth, 3) daily sugar intake, 4) salivary flow, 5) patient oral hygiene, 6) water fluoridation, 7) whether the patient is currently taking certain medications, 8) patient age, 9) the amount of money spent recently on dental restoration (i.e. spending history — abbreviated SH), 10) the presence of orthodontic appliances, 11) whether the patient has received head and/or neck radiation, and 12) the level of *Streptococcus mutans* in the oral cavity. These factors are exemplary and the list is not intended to be exhaustive. One skilled in the art would know that other factors may well play a role in assessing patient risks relating to the occurrence and development of cariogenic disease.

The following risk factors are examples of contributing risk factors in the development of periodontal disease: 1) presence of anaerobic periodontal pathogens, 2) mobility of teeth, 3) pocket depth, 4) bleeding/inflammation of gums/pockets, 5) patient age, 6) patient oral hygiene, 7) whether the patient smokes, 8) amount of money spent recently on periodontal procedures (i.e. spending history — abbreviated SH), 9) whether the patient has diabetes, and 10) whether the patient is currently taking certain medications. These factors are exemplary and the list is not intended to be exhaustive. One skilled in the art would know that other factors may well play a role in assessing patient risks relating to the occurrence and development of periodontal disease.

The data relating to each of the risk factors is collected in one of three ways. Some factors are taken from the patient's demographic data entered into a chart or computerized system for each patient. Some factors are based on objective assessments by a dentist, and some factors are based on a subjective evaluation provided by a patient either on a questionnaire or during an interview.

Figures 1 and 2 illustrate certain preferred embodiments of the present invention for caries risk assessment and for periodontal risk assessment, respectively. This list is exemplary and not intended to be exhaustive. It is envisioned that the risk incidence may change or be augmented in view of further research. The "indicators" noted on the Figures are risk factors used preferentially in risk assessment. The charts of Figures 1 and 2 list in one column the risk factors which are determined in one of three ways. Some factors are extracted from the patient demographic data, some factors are based on an objective assessment by a dentist, and some factors are based on a subjective evaluation provided by a patient on a questionnaire. In the following column, the weighting which is assigned to that risk factor is listed depending on whether there is a spending history available for the patient. Since spending history is relevant to determining the risk of dental caries or the risk of periodontitis, each risk indicator is weighted differently if spending history is available than it is if no spending history is available for the patient.

The scoring for each patient is based on the determination of whether the risk factor is high, medium or low. If the risk factor is determined to be high, the weight (W) is multiplied by 2. If the risk factor is determined to be medium, the weight is multiplied by 1 and if the risk factor is determined to be low, the weight is multiplied by 0. For example, active caries are determined by an examination performed by a dentist. If the patient is determined to have two or more open lesions, the risk indicator is high and the weight is multiplied by 2. If there are no open lesions, the risk is low and the weight is multiplied by 0.

The general formula applied is:

where RA = risk assessment;

RS = risk score;

WF = weighting factor; and

$TS_{(max)}$ = the maximum total score assuming all risk indicators are high.

As will be appreciated, this formula provides a risk assessment expressed in percent. Under this formula, any patient that scores over 75% is considered at risk of dental caries and a bacterial risk assessment to determine the *Streptococcus mutans* level of the patient's oral cavity must be performed. Suitable tests for measuring the presence and levels of *Streptococcus mutans* are well known in the art and would be known to dentists and other skilled in the art.

If the patient is found not to be at risk, a treatment plan option is determined immediately on computation of the above formula and the patient is selected for placement on the Low Risk Treatment Method option. If it is determined that the patient has one of the factors that always indicates the need for a Caries Bacterial Risk Assessment, namely for example: recent restorative spending on the patient is in the high category; the patient has more than two active caries; the patient is taking medications which increase the risk

of dental caries; the patient has orthodontic appliances; or the patient has recently suffered from cancer of the head or neck; then it is still determined that the patient is "at risk" and a *Streptococcus mutans* test is performed.

The determination of whether a patient is "at risk" of cariogenic disease therefore depends on exceeding a threshold value determined by a risk assessment formula; however, certain other factors such as those listed above may always indicate that the patient is "at risk" even if the threshold level has not been exceeded. One skilled in the art would know of other factors that would trigger a bacterial or periodontal risk assessment even though a threshold value is not met. One skilled in the art would also appreciate that other factors are known or will be known to always put a person at risk of cariogenic disease or periodontal disease.

The risk indicators relating to recent restorative spending and age are extracted from the patient demographic data. Age, for example, can be calculated by the central processor in a computerized system by determining the difference between the patient's date of birth and the system date of the processor. The postal code, zip code or other publicly available indicator selected from the patient demographic data is used in a table lookup to determine whether the patient's water source is fluoridated. This table is maintained from statistics publicly available on municipal water supplies. This determination of patient water fluoridation can also be determined by a central processor, when a computerized system is used, by a similar comparison of patient postal code, for example, with a table of postal codes which indicates the level of water fluoridation in the area.

Listed below are descriptions of the dental risk factors appearing in Figure 1. Two or more lesions of any of the active caries D1-R result in a high score for the patient. One or more lesion of any of the active caries D1-R results in a medium score. All other factors are self-explanatory.

Active Caries

D1 = Incipient caries/white spots.

D2 = Enamel caries.

D3 = Dentinal caries.

D4 = Pulpal involvement.

R = Root caries.

Record if Patient has either: no lesions, white spots or open lesions.

DMFT (Decayed, Missing or Filled Teeth)

Based on 28 teeth. Teeth not counted are: Third molars, unerupted teeth, congenitally missing and supernumerary teeth, teeth removed for reasons other than dental caries, teeth restored for reasons other than caries, primary tooth retained.

Frequency of Daily Sugar Intake

Frequency of sugar intake between meals.

Low = Rarely.

Medium = 1-2 times per day.

High = 3 or more times per day.

Salivary Flow

This factor involves both the quantity (amount), and quality (thick or thin), of saliva

Below Average = dry mouth with scanty saliva, and coated tongue.

Average = Mouth well lubricated.

Above Average = High quantity of saliva.

Oral Hygiene

Includes measurements of both soft and hard deposits.

Soft = Plaque, material, and food debris.

Hard = Calculus.

0 = No soft or hard deposits.

1 = Soft and/or hard deposits covering < 1/3 of the tooth surface.

2 = Soft and/or hard deposits covering > 1/3 but < 2/3 of the tooth surface.

3 = Soft and/or hard deposits covering > 2/3 of the tooth surface.

Orthodontics

Is the patient wearing fixed orthodontic appliances — or no?

Medications

Is the patient on medication which could contribute to xerostomia (dry mouth) for any of the following conditions: High Blood Pressure, Angina, Depression,

Insomnia and/or Anxiety.

Possible medications include: Ipratropium, Triamcinolone, Oxybutynin, Triazolam, Amitriptyline, Fluoxetinne, Sucralfate, Ibuprofen and/or Transderm-nitro.

Head/Neck Radiation

Has the patient been diagnosed with head or neck cancer or has the patient ever received radiation to the head or neck area for any other reason? (Yes or No)

Figure 2 shows the risk factors currently considered in assessing the risk of periodontitis. The following factors are determined by an examination by the dentist: mobility, bleeding/inflammation, and oral hygiene. The following factors are determined from an assessment by a patient reported on a questionnaire or in an interview: smoking, diabetes and medications. Age and recent periodontal spending are extracted from the patient demographic data. As discussed for Figure 1, these factors are exemplary and the list is not

intended to be exhaustive. One skilled in the art would know that other factors may well play a role in assessing patient risks relating to the occurrence and development of periodontal disease.

As in weighting the risk indicators for the risk of caries, the risk indicators for periodontitis are weighted depending on whether recent spending history is or is not available for the patient. Otherwise, all computations are identical and a periodontal bacterial risk assessment is triggered if the low risk factor score is greater than 75%; there is high periodontal spending in the last two, 12 month periods; or, the patient has tooth mobility and inflamed gums.

When assessing the risk factors relating to periodontal disease in preferred embodiments the factors are assessed as follows.

Tooth Mobility

Measures tooth's ability to be displaced.

M=Normal

M1=Slight Mobility (greater than normal)

M2=Moderate Mobility (greater than 1 mm displacement)

M3=Severe Mobility (may move in all directions).

Bleeding/Inflammation

0=Normal Gingiva

1=Mild Inflammation (slight change in colour, slight edema, no bleeding on probing)

2=Moderate Inflammation (redness, edema and glazing, bleeding on probing)

3=Severe Inflammation (marked redness and edema, ulceration, tendency to spontaneous bleeding)

Smoker

Assess the number of cigarettes, pipes or cigars per day:

non-smoker

1 to 10

11 to 20

21 to 25

greater than 25

Diabetic

Is this patient diabetic — yes or no?

Treatment is tailor[illegible]fectively control disease and to prevent disease fro[illegible] worsening. A [illegible]matic and ordered methodology is provided whereby a dental care provider is conducting a comprehensive dental health examination for each patient on a treatment plan. Treatment approaches have been standardized taking into account known risk factors and managed by way of a database system.

Such a system includes means for accepting and storing a plurality of predefined variables representing risk factors relevant to oral disease and means for computing a risk assessment value using the predefined variables and a predefined weight factor assigned to each variable, whereby the risk assessment value is used as a variable for determining the treatment option selected. Preferably, the system is defined by a central processor, a database associated with the central processor and a plurality of satellite stations connected to the central processor by a data communications link, whereby programs for accepting and storing the plurality of predefined variables, computing the risk assessment value and selecting the treatment option reside and are executed at the central processor. The computer system can further be defined as comprising a file server having a central processing unit and a dynamically accessible memory for storing a database, a plurality of satellite stations adapted to connect to the file server through a data communications service, means at the file server for storing dental patient demographic data in the database, means at the file server for accepting and storing a plurality of

predefined variables representing risk factors relevant to a given patient's risk of oral disease and means for downloading a form/questionnaire from the file server to a satellite station through the telecommunications service, the questionnaire being adapted to accept the predefined variables, the predefined variables being uploaded to the file server through the telecommunications service after the variables have been entered.

Figure 3 is a schematic diagram of a computerized system configured in accordance with a preferred embodiment of the invention. The system includes a server 20, a database 22 associated with the server 20, and a plurality of satellite stations 24. The server 20 may be a Unix or a Personal Computer based machine, each of which are well known in the art. The database 22 is preferably stored on a mass storage medium, such as a hard disk of another computing machine (not illustrated) that is isolated from the server 20 by a firewall 28. The server 20 is preferably configured as a world wide web site, in a manner well known in the art, and is hereinafter referred to simply as a "web server 20". Satellite stations 24 communicate with the web server 20 through a data communications service 26, such as the Internet. The satellite stations 24 are typically personal computers (PCs). In the alternative, they may be unix workstations or any other computing device capable of accessing a data communications service, such as the World Wide Web on the Internet. The only software relevant to the invention that is installed on the satellite stations 24 is a world wide web site browser such as Netscape 2.01, available from Netscape Corporation of Mountain View, California, U.S.A. It will be apparent to persons skilled in the art that the system configuration shown in Fig. 3 is not a client/server architecture. The architecture is more accurately described as a virtual private network.

All application software relevant to the invention is concentrated at the web server 20 and all dental patient demographic data and preventive treatment data resides on database 22 behind the firewall 28. This arrangement has several advantages. For example, maintenance cost and development cost for the software are minimized because the software is

concentrated on the single web server 20. In addition, program upgrades and enhancements are instantly available to satellite stations 24. Costs are minimized because software distribution costs are eliminated and backwards compatibility restraints are virtually eliminated. The data available on database 22 also provides an invaluable concentration of patient demographic and prevent[illegible]ment data that is useful in research and evaluation to ensure that risk assessment and preventive treatment methods are effective.

Figures 4A and 4B show a simple overview of the principal operations the web server 20 shown in Fig. 3 The web server 20 is configured to accept communic[illegible]packets at port 80 of its 64 K telecommunications ports. Packets addr[illegible]o other ports are ignored and dropped. In a step 40, the web server 20 monitors port 80 to determine whether a TCP/IP packet addressed to that port has been received. This a cyclical process handled by the operating system. If a packet is received on port 80, a determination is made in step 42 as to whether the packet contains a connect request. If not, it is determined whether the packet is related to an active session in step 44. The web server 20 is provided with an operating system such as, for example, Windows NT available from Microsoft Corporation, U.S.A. Other operating systems such as any of the many version of the Unix operating system are also equally adapted to tracking and controlling a plurality of simultaneous TCP/IP sessions in a manner well known in the art. If it is determined in step 44 that the packet is not related to an active session, the packet is dropped in step 46. If the packet is related to an active session, the process is transferred to a packet processing step 62 (see Fig. 4B), which will be described below in more detail.

If the TCP/IP packet was determined to contain a connect request in step 42, a logon form is downloaded in step 48. All data input requests in accordance with the invention are preferably forms which are downloaded to the satellite stations 24 in a manner well known in the art. The forms are preferably created using HyperText Markup Language (HTML) which is a standard language used for web-based forms and is well known in the art.

Using HTML, field edits may be embedded in the forms to ensure that all required data entry fields are completed with inacceptable ranges before the forms are uploaded to the web server 20. This minimizes error checking at the web server 20 and also minimizes retransmission of communications packets so that efficiency is maximized. Many software tools are available to assist in the creation of the software applications on the web server 20. For example, the Oracle Web Agent available from Oracle Corporation in Redwood City, California, U.S.A. and the Oracle Designer 2000 Case Tool also available from Oracle Corporation may be used for this purpose. Many other similar tools are likewise available and equally adapted to facilitating the development of the applications on the web server 20.

After the logon form is downloaded in step 48, the system receives a packet containing a user ID and password which is validated in step 50. If the user ID and password are not valid, a logon attempt counter is incremented in step 52 and the counter is examined to determine whether more than three logon attempts have been made. If it is determined in step 54 that less than three logon attempts have been made, an invalid ID or password message is downloaded in step 56 and the system waits for a new attempt. If it is determined that a logon has been attempted more than three times, an access denied message is downloaded in step 55 and the system ends the session in step 66 and releases all allocated resources in step 68 (see Fig. 4B). If in step 50 the user ID and password are determined to be valid by a table lookup in a table of registered users having preassigned user IDs and associated passwords, a startup form is downloaded in step 58 which provides users with a menu of initial options for using the system. In step 60, a web server 20 waits for a next session packet. In step 62, the packet is examined to determined whether it is a log off request. If not, the request is processed in step 64. Processing depends on the user selection as will be discussed below in more detail. If the log off request is received as determined in step 62, the session is ended in step 66 and all allocated resources are released in step 68.

The user options currently available on the web server 20 are shown on the following table. As explained above, user options are selected from downloaded forms in a manner well known in the art. The options currently available are add a patient; search for an existing patient by dental plan number; SIN number or name; update a patient record; perform a risk assessment; request treatment scheduling; request procedure predetermination; request patient credit or download current educational material. Each of these functions is based on well known information exchange procedures using Internet protocols. While these functions are representative of currently enabled activities, they are exemplary only and new functions may be added as dictated by requirement or demand.

USER OPTION	SYSTEM RESPONSE
Add a Patient	Download new patient form; accept new patient data; create new patient demographic record in the database
Search for Patient by Dental Plan No., SIN No. or Name	Search database given starting string; download a list of matching records; retrieve patient record using pointer selected by user
Update a Patient Record	Download patient input form; accept patient data; update patient record in database
Perform Risk Assessment	Download risk assessment form; accept variables; compute risk assessment; download assessment results and preventive treatment option, when applicable
Request Treatment Scheduling	Download appointment ranges based on patient's treatment option
Request Procedure Predetermination	Download predetermination form; accept predetermination variables; effect advisements; return predetermination information
Request Patient Credit	Download credit request form; accept credit variables, initiate credit approvals; return credit decision
Print Reports	Download report request form; accept report request parameters; extract report data from database; format and download report
Access Current Educational Material	Download educational material request form; accept request parameters; download formatted educational material

Any authorized user, typically a dentist or dentist's assistant, at a satellite station 24 may add a new patient by requesting a new patient input

form which is downloaded from the web server 20. As described above, the new patient input form includes embedded HTML commands which edit the input in each required field to ensure that all required fields are completed and that the data input in each field is within an acceptable range. After the form is completed, it is uploaded to the web server 20 which accepts the data packets and updates the database 22. As described above, the database 22 is isolated from the public network 26 by a firewall 28. Firewall 28 is a computing machine configured to communicate with the web server 20 on a port other than port 80, to which the web server 20 responds to communications from the Internet. This configuration is to ensure that access to the database 22 is denied from the public network 26. A firewall 28 operates on principles well known in the art. Firewalls are available from many vendors.

An authorized user at a satellite station 24 can also search for an existing patient record using search fields including a dental plan number, a social insurance number, or the patient's name. Searching is initiated through a search form downloaded from the web server 20. The web server accepts the search parameters and downloads a list of matching patient records from which the authorized user at the satellite station 24 selects a desired record that is retrieved by the web server from the database 22 and downloaded to the satellite station 24.

The authorized user at a satellite station 24 may also update a patient record. To accomplish this, the patient input form is downloaded with the existing patient record. Certain fields in the existing patient record are modifiable to permit the authorized user to correct address information or telephone numbers, for example. When the correction is complete, the patient data is uploaded to the web server 20 which updates the patient record in the database 22.

An authorized user 24 may also perform a risk assessment which has been described in detail with reference to Figures 1 and 2. To perform a risk assessment, a risk assessment form is downloaded from the web server 20.

The risk assessment form is completed by the authorized user at the satellite station 24 and uploaded to the web server 20 which computes a risk assessment level and downloads the results, as well as a preventive treatment option based on the results, as is also described below.

An authorized user at a satellite station 24 may also request treatment scheduling as will also be explained in more detail below. In treatment scheduling, appointment ranges based on a treatment option are downloaded to the requesting satellite station 24. After an appointment is made using the appointment ranges, the appointment date and hour is stored in a database 22 so that information is available in a report form as will be explained below.

An authorized user can also perform a request procedure predetermination. Certain dental procedures must be preapproved by an insurer before they can be scheduled or performed. The system facilitates this process by downloading a predetermination form on request and accepting predetermination variables such as the procedure code, the reason for the procedure request, the projected cost and any other information relevant to procedure approval. When this information is uploaded to the web server 20, the web server effects any advisements to the insurer to initiate procedure review. For example, a copy of the form may be downloaded for review and approval via E-mail or facsimile, as appropriate. The detailed procedures for insurer predetermination depend on the insurer and available facilities, as will be appreciated by those skilled in the art. When the insurer returns a predetermination response, the response is downloaded to the authorized user's satellite station 24.

The system is also enabled to permit authorized users at satellite stations 24 to request patient credit for expensive procedures which are not covered by an insurer or for which only a portion of the expense is covered by an insurer. A credit request form is downloaded from the web server 20 on demand. The authorized user completes the credit request form with information provided by the patient. On receipt of the credit variables, the web server 20 initiates credit approval procedures which include contacting an

institution such as a bank or credit union which has agreed to extend the credit to patients assuming that their credit rating is acceptable. The request form is downloaded to the institution's computer system, which may be web server, or the like, and the institution processes the request. The processing normally involves contacting a credit rating agency to determine the credit rating of the patient. The credit request is then accepted or rejected and an advisement is sent back to web server 20 which forwards the advisement to the authorized user at the satellite station 24.

Authorized users may also print reports such as a patient and dental office fees summary which provides a listing of the authorized user's patients in the database 22 and a summary of dental office fees related to each patient over a specified period of time. A projected dental office fees report is also available which projects dental office fees for the authorized user based on scheduled treatments over a specified period of future time. A healing success history report is also available which shows the success over a specified period of time of the preventive treatment for those patients under the care of the authorized user. A scheduled appointment report is also available to provide the authorized user with a list of all scheduled appointments for a specified time period. Other reports may be made available as demand requires. When an authorized user at a satellite station 24 wishes to print a report, a report request form is downloaded from the web server 20 and the web server 20 accepts the report request parameters from the satellite station 24. The web server 20 then extracts report data from the database 22, formats and downloads the report to the satellite station 24.

An authorized user at satellite station 24 may also access current educational material. Current educational material is maintained in the database as part of the service to provide authorized users and their patients with useful educational material. Product literature may also be made available. Educational material selected from a request form is downloaded from the web server 20 on demand. The educational material may include printed text graphics, or multimedia materials useful in educating practitioners

and their patients.

PATIENT EDUCATION

In accordance with the present invention, specific patient education is supplied to the patient from the computerized system based on the risk assessment for that patient and is updated upon each visit to the dental office. Examples of topics covered include: Oral Hygiene, Sugar Intake, Smoking, Bacteria, and Salivary Flow as well as a statement of an overall dental fitness score.

Patient education and participation are important to the overall process of achieving dental wellness. The computerized system of collecting and inputting specific data relating to risk factors for patient oral health permits the standardization of patient advice based on the weaknesses and strengths identified for that particular patient. The computerized system of patient management which is used in the present invention for computing caries and periodontal risk assessments permits the rapid and easy generation of feedback for the patient describing the steps they should take to improve upon the weaknesses and/or the strengths that have been identified by way of specific patient feedback.

Messages can be generated for any of the factors which have been identified and the message will reflect the specific patient's risk for that factor. The patient therefore receives high quality consistent information about the steps that he or she needs to take in order to improve his or her oral health. The messages that are generated can also specifically acknowledge changes which have occurred between visits. Again the patient receives consistent high quality feedback and information on their own specific oral health in a format that they can take with them.

If the patient is being treated with antibiotics then the system can automatically generate a form for the patient that describes the nature of the medication, the dosage, certain precautions, possible side effects and other instructions about taking the medication to completion. An example of such a form is Form 2.

Further details of the preferred embodiments of the invention are illustrated in the following Examples. The Examples are presented for the purpose of illustrating the invention and are not intended to limit the scope of the invention as defined in the appended claims.

Some of the Examples below incorporate preferred products sold by Knowell Periodontal Technologies, Inc., and its Bana™ brand of enzymatic test kit for detecting hydrolysis of benzoyl-DL-arginine-naphthylamide.

EXAMPLES

Example 1: Conducting a Periodontal Bacterial Assessment Test

Each bottle of BANAÔ brand test strips contains directions of use, including photographs of each important step.

1. Remove the Bana Test strip from the dispensing bottle.
2. Record the desired tooth and site information on the Bana Test strip.
3. Remove supragingival plaque prior to sampling.
4. Using a curette, sample subgingival plaque and place specimen onto the raised white reagent matrix affixed to the lower portion of the test strip, opposite tooth and site number of the sample which you have previously marked on the test strip. Note it is not important to the test results, where you sample the plaque in the pocket, nor how much plaque you sample. The more plaque that is removed, the greater the possibility of a positive test result; in addition, if too much plaque is sampled, the sides of the test strip may stick together when folded. Thus, it is best to test only that plaque that is removed by one passage of the curette over the root surface. Even if no plaque can be visualized on the curette, there is usually enough plaque to give reliable test results. Ensure accurate sampling and recording.
5. Before taking another plaque specimen, wipe the curette on a clean piece of cotton or other suitable wipe to prevent carry-over of plaque. Note that one Bana Test strip will accommodate four sites of plaque specimens.
6. After all desired sites have been sampled, moisten the upper buff colour test matrix with distilled water using a cotton ball or applicator bottle. Note tap water is not reliable as various impurities may interfere with colour

development of the test.

7. Fold the test strip at the perforation so that the white lower and buff upper matrices come in direct contact with each other.

8. Set the Incubator to position 1, 2 or 3 as desired and according to the patient profile described in Table 3 below.

9. Place the folded test strip into the slot on the top of the Incubator and wait accordingly for the results. The incubator is working when the light goes on.

10. When the Incubator light indicates (by turning off) that the test strip's heating period is complete, separate the lower white portion of the test strip at the perforation and discard this portion of the strip as Hazardous Waste according to CDC Guidelines. Caution: This lower portion of the Bana Test strip may contain traces of pathogenic bacteria, viruses, and b-naphthylamine, a product of BANA-enzyme hydrolysis which is believed to be carcinogenic.

11. Read the test results on the upper matrix according to the Reagent Test Card provided with each dispensing bottle of Bana™ brand test strips. Record the results for each sampled site as negative, weak positive or positive. Record result in the patient's chart and/or preserve the Bana Test strip by sealing the upper buff strip with clear, non-porous tape and attach to the patient's chart for future reference. The blue colour is permanent.

Example 2: Interpreting the Knowell Bana™ Brand Test Results

The test results may have differing significance between patients and should be considered from interval to interval for each patient and within the context of the patient's clinical record of periodontitis, gingivitis, overall oral hygiene and compliance to home care, and overall general health. Dental professionals should use their clinical judgment in interpreting test results. In particular, because the BANA-enzyme positive bacteria may exist as microcolonies in only part of the plaque sample, the clinician should pay attention to the intensity of the colour as well as the area of the colour reaction. The following Table shows the range of bacteria levels according to the three different test results.

Bacteria Levels by Bana Test Result

Negative Test Result	Weak Positive Test Result	Positive Test Result
No blue colour on buff matrix	Small, faint blue spots on buff matrix	Distinct blue patches on buff matrix
P. gingivalis $<10^4$ CFU	*P. gingivalis* $>10^4$ CFU	*P. gingivalis* $>10^5$ CFU
T. denticola $<10^4$ CFU	*T. denticola* $> 10^4$CFU	*T.denticola* $> 10^5$ CFU
B. forsythus $<10^4$ CFU	*B. forsythus* $> 10^4$ CFU	*B. forsythus* $> 10^5$ CFU

cfu= colony forming units

Note that bacteria levels are dependent on the size of plaque sample

Weak Positive Reaction: This appears as a faint blue colour over a very small area or over the entire area of contact with the plaque. Such a colour intensity indicates the presence of one or more of the BANA-enzyme test positive species. The significance of this result depends on:

·.the presence or absence of clinical symptoms of periodontal inflammation, and

·.the patient's history of periodontal disease

Generally, a weak positive result in a patient asymptomatic of the disease and without previous periodontal difficulties, confirms that low levels of these bacteria are present and the patient has low risk. However, a weak positive result in a symptom-free patient who has a history of periodontal disease and is now on recall maintenance may indicate re-colonization with pathogenic bacteria -- medium risk. Additional preventive measures may then be required for this patient.

Positive Reaction: This appears as a distinct blue colour over a very small area or over the entire area of contact with the dental plaque. Note that there will be

more positive reactions in Setting 3 (15 minutes at 55°C) indicating infections above 500,000 of the anaerobes. Such levels are often seen in patients with either clinical periodontal disease or a history of periodontal disease or both. This is a high risk situation.

Negative Reaction: This indicates no anaerobic infection or anaerobic infections below the range of 10,000 to 100,000 at the site of sampling. These low levels confirm a clinical judgment of health or adequate deep scaling.

Occasionally, some of the plaque sample will transfer to upper test matrix during the incubation of the strip; frequently, this is caused if there is too much plaque being sampled. This may obscure the test result. The dental professional may generally note the blue colour of a positive test result around the periphery of the transferred sample. If the test is unreadable, repeat the test.

Example 3: Specifications of the Knowell Bana™ Brand Test

The test is a plastic strip to which are attached two separate reagent matrices. The lower white reagent matrix is impregnated with N-benzoyl-DL-arginine-b-naphthylamide (BANA). Subgingival plaque samples are applied to these lower matrices. The upper buff reagent matrix contains a chromogenic diazo reagent which reacts with one of the hydrolytic products of the enzyme reaction forming a blue colour. The blue colour is a positive or weak reaction, appears in the upper buff matrix and is permanent.

The test is based on a modification of the BANA-enzyme hydrolysis test of Loesche et al. (W. Loesche et al., "Bacterial Profiles of Subgingival Plaques in Periodontitis", J.Periodontol, 56, 1985, pp. 447-456 and W. Loesche et al, "Trypsin-Like Activity in Subgingival Plaque -- A Diagnostic Marker for Spirochaetes and Periodontal Disease?", J.Periodontol, 58, 1987, pp.266-273.) The anaerobic bacteria Porphyromonas (Bacteroides) gingivalis, Bacteroides forsythus and *Treponema denticola* can hydrolyze the BANA-enzyme. Given that these specific bacteria are linked to common forms of adult periodontitis, a test which detects their enzymatic activity in subgingival plaque samples at discrete sites can be a useful adjunct to conventional diagnosis and management of this disease.

Principles of the Test: Peptidases in certain anaerobic bacteria can hydrolyze the peptide analog N-benzoyl-DL-arginine-2-naphthylamide (BANA). One of the hydrolytic products of this reaction is b-naphthylamine, which reacts with a diazo reagent Fast Black K producing a permanent blue colour. No other microorganisms of over 60 that have been tested, have been found to possess significant amounts of BANA-hydrolyzing enzyme. (W. Loesche et al., "Development of a diagnostic test for anaerobic periodontal infections based on plaque hydrolysis of BANA", J Clin Microbiol, 28, 1990, pp. 1551-1559.) Blood and saliva do not hydrolyze BANA and do not interfere with this test. (W. Bretz and W. Loesche, "Characteristics of trypsin-like activity in subgingival plaque samples", J Dent Res, 66, 1987, pp. 1668-1672.)

Precautions: The Knowell Bana™ test is for *in vitro* use only. To preserve the shelf-life of the test strips, ensure that the top to the dispensing bottle is put tightly back on the bottle after removing a test strip, and ensure that the desiccant is contained within the dispensing bottle. The Test strips are vulnerable to humidity and need to be stored in a humidity-controlled bottle at all times for optimal test operability.

Specimen Collection and Procedure: Anaerobic microorganisms associated with periodontal disease are found in the subgingival plaque. To obtain specimens for testing, sites should be cleared of supragingival plaque. Each specimen may be obtained from a single site or subgingival plaque from several sites around the tooth may be pooled and noted on the Test strip. A standard scaling curette (e.g. Gracey 11/12 or 13/14) may be used to obtain subgingival plaque specimens.

Materials Required But Not Supplied:

1. scaling curette (Gracey 11/12, 13/14)
2. distilled water
3. cotton balls or wetting applicator bottle
4. incubator (if test strips not purchased as part of the Knowell Bana™ brand Starter Pack)

Although preferred embodiments of the invention have been described herein,

it will be understood by those skilled in the art that variations, modifications, and equivalents may be made thereto without departing from the spirit of the invention or the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A kit for determining an individual's risk of oral disease and for selecting a treatment option comprising:

a) a risk questionnaire to be completed by an individual and the individual's dentist for assessing an individual's risk factors relevant to oral disease;

b) a computer system for calculating a risk assessment level based on the risk factors assessed using the questionnaire;

c) a treatment kit for use in a treatment option which is selected based on the risk assessment level.

2. A method for providing an index for assessing oral disease comprising;

a) assessing risk factors relevant to oral disease;

b) calculating a risk assessment level based on the risk factors of step (a); and

c) indexing the risk assessment level with treatment options.

3. A method of assessment of the risk of dental disease comprising evaluating parameters of a patient indicative of respective risk factors, weighting the risk factors, combining the weighted risk factors to produce an overall risk assessment value and selecting a treatment option on dependence thereon and in accordance with predetermined criteria.

4. Use of a fluoride in the manufacture of a medicament for the treatment or prevention of oral disease wherein the medicament is used in a method of assessing dental health comprising;

a) assessing risk factors relevant to oral disease;

b) calculating a risk assessment level based on the risk factors of step (a); and

c) selecting and initiating a treatment option comprising the use of the medicament based on the risk assessment level.

5. Use of an antibiotic in the manufacture of a medicament for the treatment or prevention of oral disease wherein the medicament is used in a method of assessing dental health comprising;

a) assessing risk factors relevant to oral disease;

b) calculating a risk assessment level based on the risk factors of step (a); and

c) selecting and initiating a treatment option comprising the use of the medicament based on the risk assessment level.

6. The kit of claim 1, additionally comprising a bacterial assessment kit for determining cariogenic bacteria and/or periodontal pathogens in an individual's oral cavity if the individual is considered to be at risk based on the ris ient level

7. of any one of claims 1 to 4 and 6, wherein the oral disease is caries.

8. The kit, use or method of claim 7, wherein the level of *Streptococcus mutans* in an individual's oral cavity is assessed as a risk factor.

9. The kit, use or method of claim 7 or claim 8, wherein the risk factors include one or more of the following:

1) presence of caries;

2) number of decayed, missing and filled teeth;

3) daily sugar intake;

4) salivary flow;

5) individual's oral hygiene;

6) level of water fluoridation in individual's water supply;

7) medications taken by individual;

8) age of individual;

9) recent spending history on dental restoration;

10) presence of orthodontic appliances; and

11) whether individual has received head and/or neck radiation.

10. The kit, use or method of any one of claims 7 to 9 wherein the treatment options comprise;

a) caries risk/low bacteria treatment option;

b) caries risk/medium bacteria treatment option; and

c) caries risk/high bacteria treatment option.

11. The kit, use or method of claim 10, wherein the caries risk/low bacteria treatment option comprises;

a) determining that the level of *Streptococcus mutans* in an individual's oral

cavity is less than 250,000 cfu/ml;

b) applying a topical fluoride varnish;

c) daily fluoride treatments for 2 months following step (b); and

d) recalling the individual for another dental risk assessment.

12. The kit, use or method of claim 10, wherein the caries/medium bacteria treatment option comprises;

a) determining that the level of *Streptococcus mutans* in an individual's oral

cavity is between 250,000 and 500,000 cfu/ml;

b) applying a topical fluoride foam;

c) applying a topical antimicrobial medication;

d) applying daily fluoride treatments for 2 months;

e) repeating steps (b) to (d) twice; and

f) recalling the individual for a dental risk assessment.

13. The kit, use or method of claim 10, wherein the caries/high bacteria treatment option comprises;

a) determining that the level of *Streptococcus mutans* in an individual's oral cavity is greater than 500,000 cfu/ml;

b) applying a topical fluoride foam and a topical antimicrobial medication;

c) repeating step (b) at approximately 7, 14 and 21 days later;

d) applying daily fluoride treatments for approximately 4 months;

e) repeating steps (b) and (d) at approximately 6, 12 and 18 months after step

(a); and

f) recalling the individual for a dental risk assessment at approximately 24 months after step (a).

14. The kit, use or method of any one of claims 1 to 3 and 5, wherein the oral disease is periodontitis.

15. The kit, use or method of claim 14, wherein the level of anaerobic periodontal pathogens in an individual's oral cavity is assessed as a risk factor.

16. The kit, use or method of claim 14 or claim 15, wherein the risk factors include one or more of the following:

1) mobility of teeth;
2) pocket depth;
3) bleeding and/or inflammation of gums or pockets;
4) age of the individual;
5) individual's oral hygiene;
6) whether individual smokes;
7) recent spending history on dental restoration;
8) whether individual has diabetes; and
9) medications taken by individual.

17. The kit, use or method of any one of claims 14 to 16, wherein the treatment options comprise;

a) moderate risk adult periodontitis treatment option;
b) high risk limited adult periodontitis treatment option; and
c) high risk extensive adult periodontitis treatment option.

18. The kit, use of method of claim 17, wherein the moderate risk adult periodontitis treatment option comprises;

a) determining that anaerobic periodontal pathogens are present in an individual's oral cavity;
b) charting periodontal pockets greater than 2mm in diameter and scaling on all pockets greater than 2mm in diameter;
c) determining if anaerobic periodontal pathogens are still present in the individual's oral cavity; and

d) if anaerobic periodontal pathogens are still present and the individual exhibits clinical signs and symptoms, administer a course of appropriate local antibiotic to the individual.

19. The kit, use or method of claim 17, wherein the risk limited and high risk extensive adult periodontitis treatment options comprise;

a) determining that anaerobic periodontal pathogens are present in an individual's oral cavity;

b) charting periodontal pockets greater than 2mm in diameter and scaling on all pockets greater than 2mm in diameter;

c) determining if anaerobic periodontal pathogens are still present in the individual's oral cavity; and

d) if anaerobic periodontal pathogens are still present and the individual exhibits clinical signs and symptoms, administer a course of appropriate systemic antibiotic to the individual.

20. The kit, use or method of any one of the previous claims, wherein the risk assessment level is calculated by a computer system comprising a central processor, a database associated with the central processor, and a plurality of satellite stations connected to the central processor by communications links, whereby programs for accepting and storing the plurality of predefined variables, computing the risk assessment value and selecting the treatment option reside and are executed at the central processor.

21. The kit, use or method of claim 20, wherein the database stores all patient demographic data.

22. The kit, use or method of claim 20 or 21, wherein the computer system includes means for scheduling appointments to effect treatment in accordance with the treatment option.

23. The kit, use or method of any one of claims 20 to 22, wherein input forms/questionnaires for accepting risk factor data are downloaded from the central processor to the satellite stations and the risk factor is uploaded from the satellite stations to the central processor for calculating the risk assessment level and selecting a treatment option.

24. The kit, use or method of any one of claims 20 to 23, wherein one of the risk factors is the level of water fluoridation in the patient's water supply, and the value of this risk factor is determined by the central processor by comparing the patient's postal code with a table of postal codes that indicate the level of fluoridation in the patient's water supply.

25. The kit, use or method of any one of claim 20 to 24, wherein one of the risk factors is the patients' age, and the value of this risk factor is derived by the central processor by calculating the difference between the patient's date of birth and the system date of the central processor.

26. The kit, use or method of any one of claims 1 to 20, wherein the computer system comprises;

a) a file server having a central processing unit and a dynamically accessible memory for storing a database;

b) a plurality of satellite stations adapted to connect to the file server through a data communications service;

c) means at the file server for storing dental patient demographic data in the database;

d) means at the file server for accepting and storing a plurality of predefined variables representing risk factors relevant to a given patient's risk factors of oral disease; and

e) means for downloading a form/questionnaire from the file server to a satellite station through the telecommunications service, the form being adapted to accept the predefined variables, the predefined variables being uploaded to the file server through the telecommunications service after the variables have been entered.

27. The kit, use or method of claim 26, wherein the satellite stations are personal computers.

28. The kit, use or method of claim 26 or 27, wherein the data communications service is the Internet.

29. The kit, use or method of any one of claims 26 to 28, wherein the computer system includes means for scheduling appointments to effect

treatment in accordance with the treatment option.

FIG. 1

Risk Indicator	**Weighting**	**Scoring**		
Caries	S.H./no S.H.	High (W x 2)	Medium (W x 1)	Low (W x 0)
Active Caries	29 / 36	2 or more Lesions	1 Lesion	No Lesion
Recent Restorative Spending	19 / 0	> $300 in last 2, 12 month periods	$200-$300 in last 2,12 month periods	<$200 in last 2, 12 month periods
Decayed, Missing or Filled Teeth	13 / 16	5 or more	3 to 4	2 or less
Daily Sugar Intake	11 / 14	High	Medium	Low
Salivary Flow	8 / 10	Below Average	Average	Above Average
Oral Hygiene	7 / 9	2 or 3	1	0
Fluoride	5 / 6	No Fluoridation	N/A	Fluoridation
Medications	5 / 6	Medicated	N/A	Non-Medicated
Age	3 / 3	> 55	45 - 55	< 45
Total	*100/100*			

FIG. 2

Risk Indicator	Weighting	Scoring		
Periodontitis	S.H./no S.H.	High (W x 2)	Medium (W x 1)	Low (W x 0)
Mobility	25 / 28	M2 and M3	M1	M
Bleeding/Inflammation	18 / 20	2 and 3	1	0
Oral Hygiene	13 / 14	2 and 3	1	0
Age	13 / 14	> 55	45 - 55	< 45
Smoking	11 / 12	Smoker > 2	Smoker 1	Non-Smoker
Recent Perio Spending	10 / 0	> $300 in last 2, 12 month periods	$200-$300 in last 2, 12 month periods	<$200 in last 2, 12 month periods
Diabetes	7 / 8	Diabetic	N/A	Non-Diabetic
Medications	3 / 4	Medicated	N/A	Non-Medicated
Total	*100/100*			

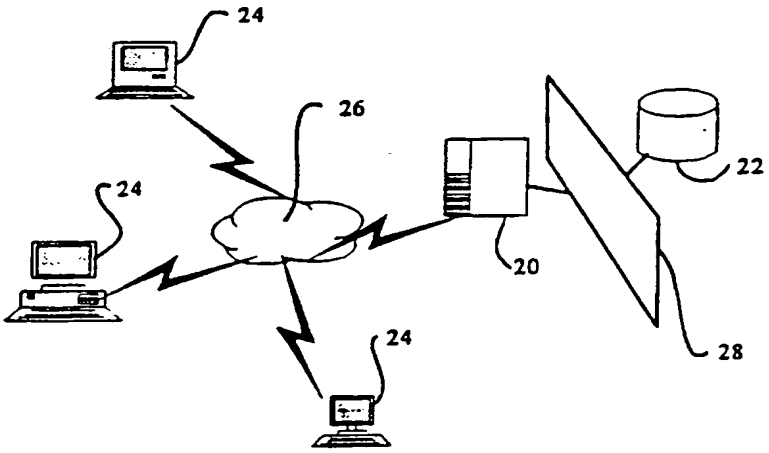

FIG. 3

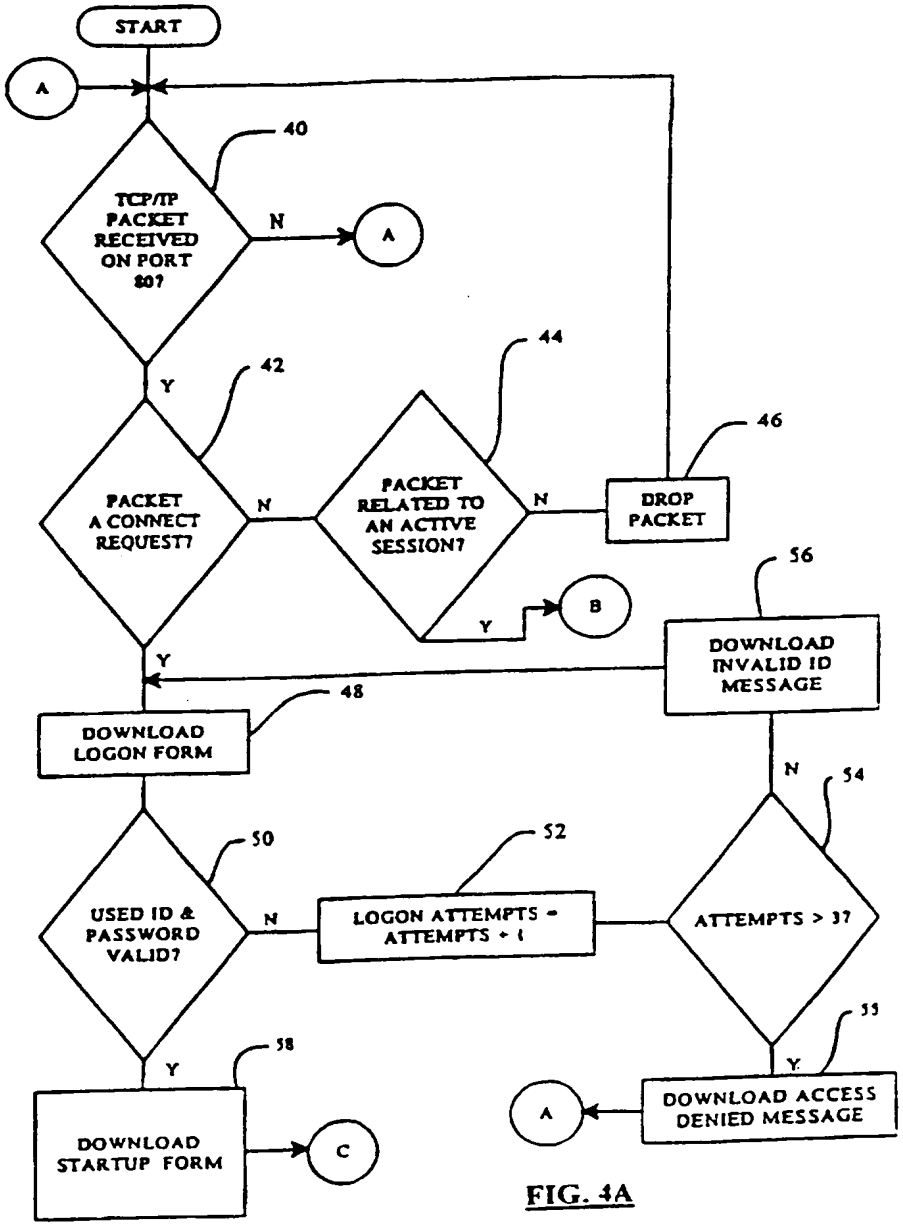
START
A
40
TCP/IP PACKET RECEIVED ON PORT 80?
N
A
Y
42
PACKET A CONNECT REQUEST?
N
44
PACKET RELATED TO AN ACTIVE SESSION?
N
46
DROP PACKET
Y
B
56
DOWNLOAD INVALID ID MESSAGE
Y
48
DOWNLOAD LOGON FORM
N
54
50
USED ID & PASSWORD VALID?
N
52
LOGON ATTEMPTS = ATTEMPTS + 1
ATTEMPTS > 3?
55
Y
Y
58
DOWNLOAD STARTUP FORM
C
A
DOWNLOAD ACCESS DENIED MESSAGE

FIG. 4A

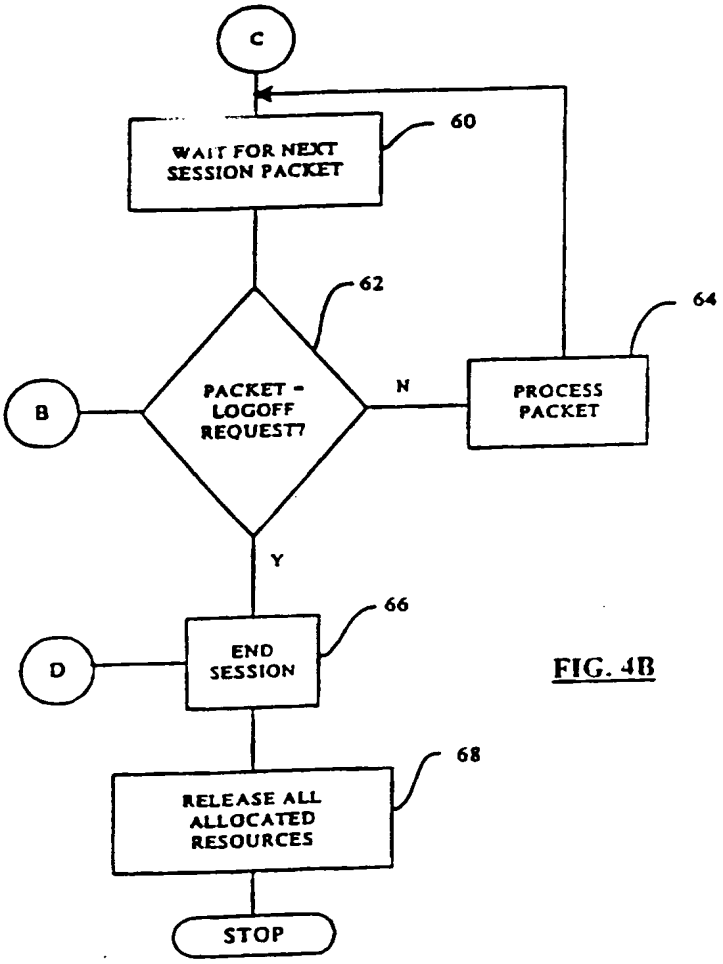
C
WAIT FOR NEXT SESSION PACKET
60
62
64
B
PACKET = LOGOFF REQUEST?
N
PROCESS PACKET
Y
66
D
END SESSION
68
RELEASE ALL ALLOCATED RESOURCES
STOP

FIG. 4B

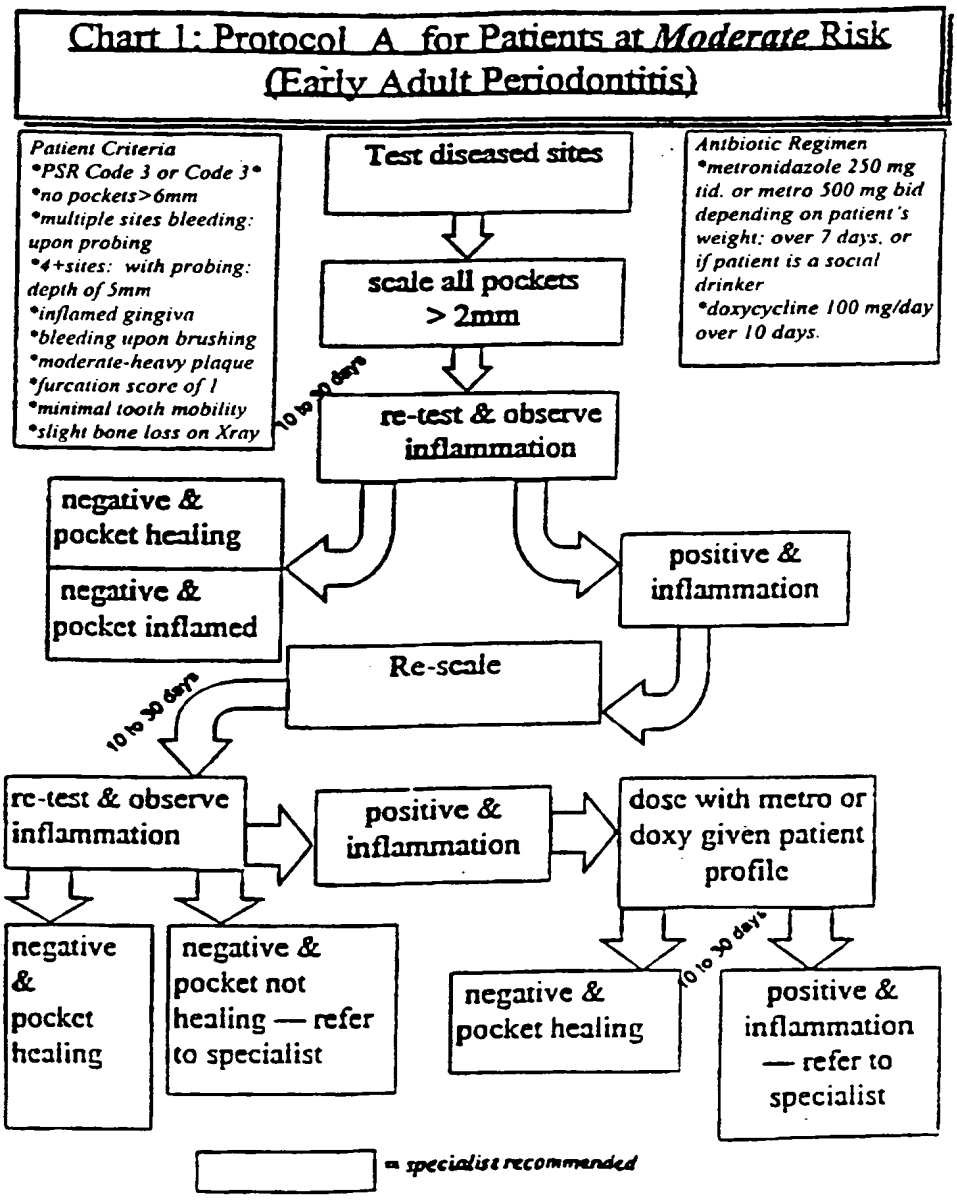
Chart 1: Protocol A for Patients at Moderate Risk (Early Adult Periodontitis)
Patient Criteria
PSR Code 3 or Code 3
*no pockets>6mm
*multiple sites bleeding: upon probing
*4+sites: with probing: depth of 5mm
*inflamed gingiva
*bleeding upon brushing
*moderate-heavy plaque
*furcation score of 1
*minimal tooth mobility
*slight bone loss on Xray
Test diseased sites
scale all pockets > 2mm
Antibiotic Regimen
*metronidazole 250 mg tid. or metro 500 mg bid depending on patient's weight: over 7 days, or if patient is a social drinker
*doxycycline 100 mg/day over 10 days.
10 to 30 days
re-test & observe inflammation
negative & pocket healing
negative & pocket inflamed
positive & inflammation
Re-scale
10 to 30 days
re-test & observe inflammation
positive & inflammation
dose with metro or doxy given patient profile
negative & pocket healing
negative & pocket not healing — refer to specialist
10 to 30 days
negative & pocket healing
positive & inflammation — refer to specialist
= specialist recommended

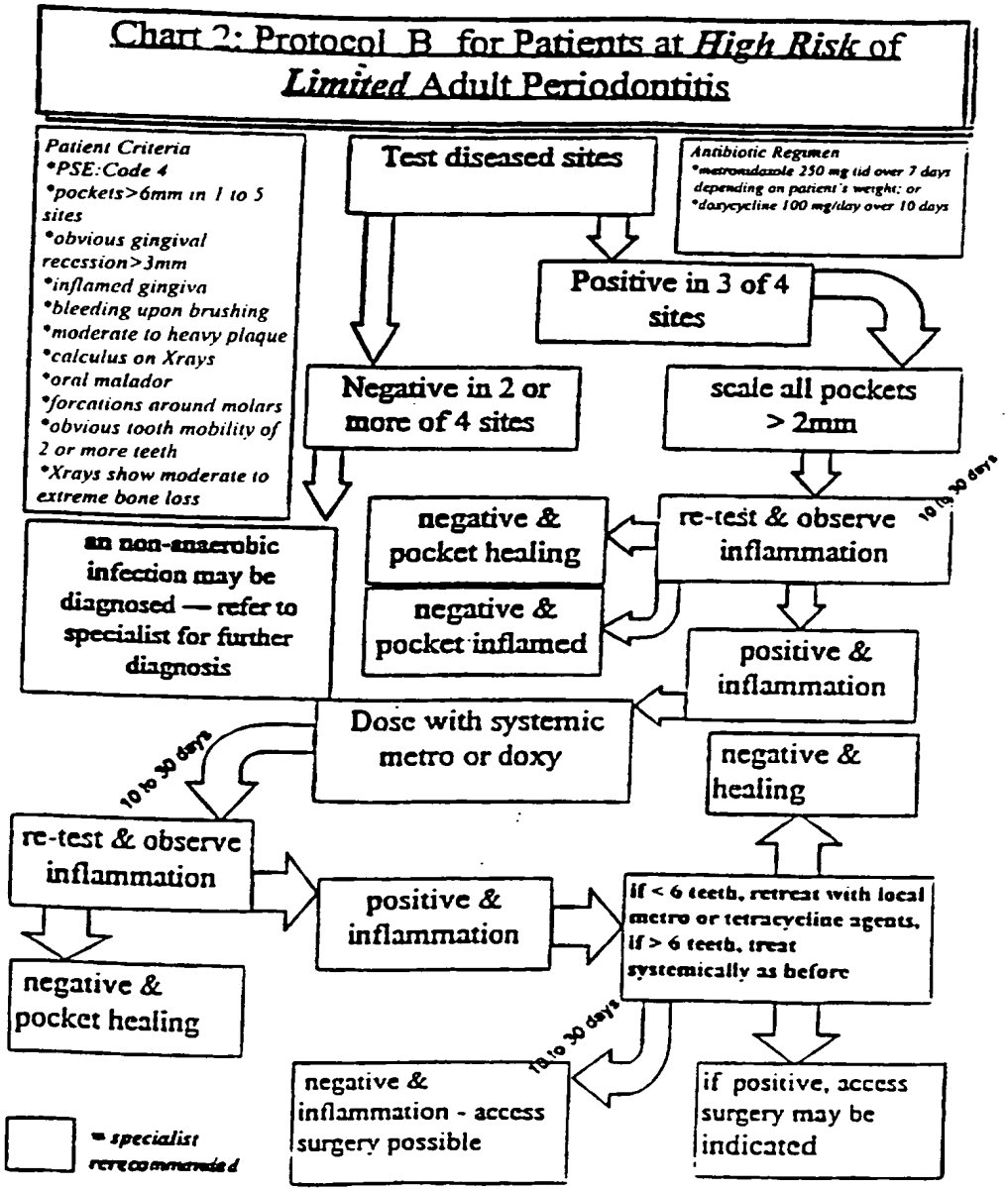
Chart 2: Protocol B for Patients at High Risk of Limited Adult Periodontitis
Patient Criteria
*PSE:Code 4
*pockets>6mm in 1 to 5 sites
*obvious gingival recession>3mm
*inflamed gingiva
*bleeding upon brushing
*moderate to heavy plaque
*calculus on Xrays
*oral malador
*forcations around molars
*obvious tooth mobility of 2 or more teeth
*Xrays show moderate to extreme bone loss
Test diseased sites
Antibiotic Regimen
*metronidazole 250 mg tid over 7 days depending on patient's weight; or
*doxycycline 100 mg/day over 10 days
Positive in 3 of 4 sites
Negative in 2 or more of 4 sites
scale all pockets > 2mm
an non-anaerobic infection may be diagnosed — refer to specialist for further diagnosis
negative & pocket healing
re-test & observe inflammation
10 to 30 days
negative & pocket inflamed
positive & inflammation
Dose with systemic metro or doxy
negative & healing
10 to 30 days
re-test & observe inflammation
positive & inflammation
if < 6 teeth, retreat with local metro or tetracycline agents, if > 6 teeth, treat systemically as before
negative & pocket healing
10 to 30 days
negative & inflammation - access surgery possible
if positive, access surgery may be indicated
= specialist recommended

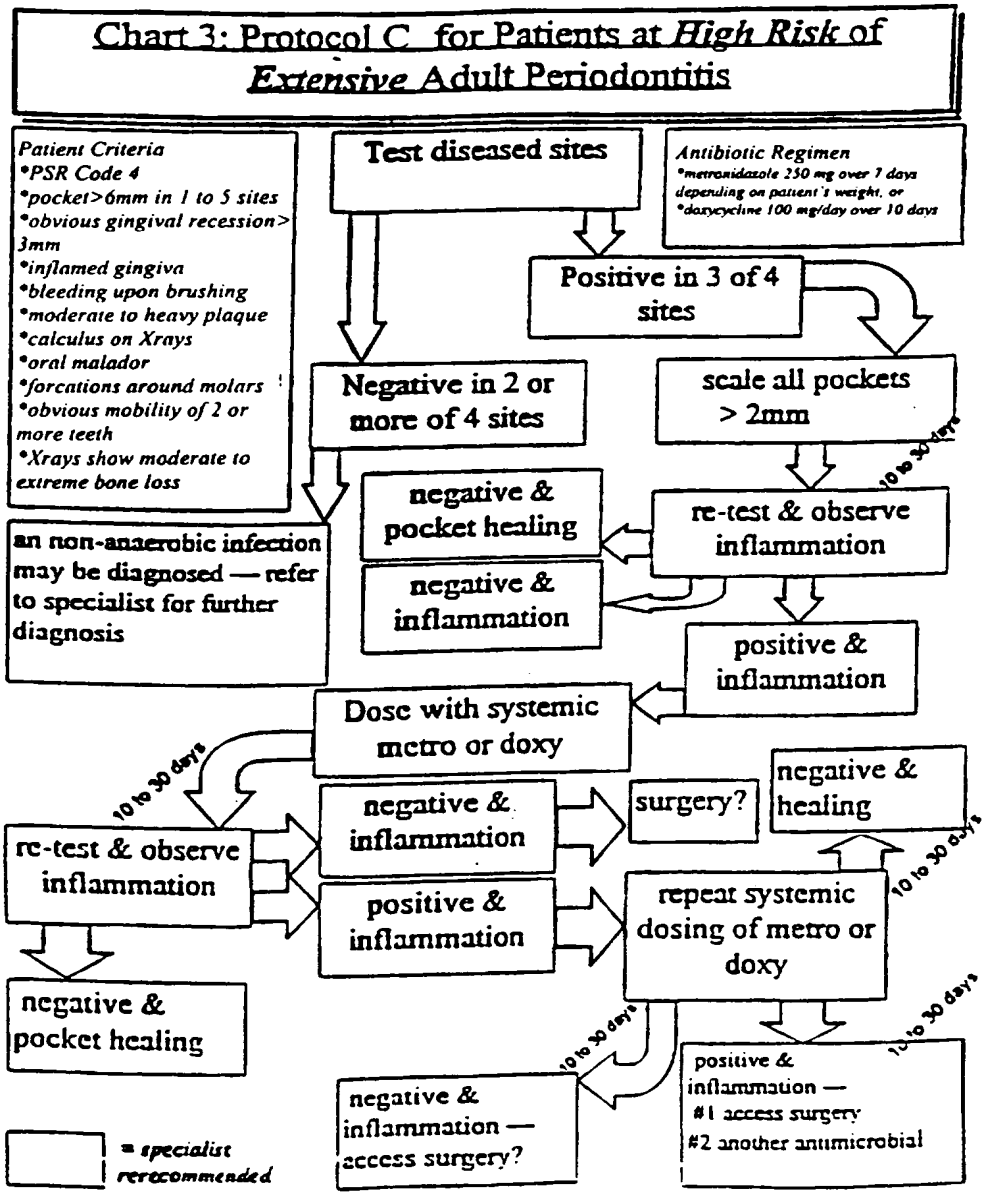
Chart 3: Protocol C for Patients at High Risk of Extensive Adult Periodontitis
Patient Criteria
*PSR Code 4
*pocket>6mm in 1 to 5 sites
*obvious gingival recession> 3mm
*inflamed gingiva
*bleeding upon brushing
*moderate to heavy plaque
*calculus on Xrays
*oral malador
*forcations around molars
*obvious mobility of 2 or more teeth
*Xrays show moderate to extreme bone loss
Test diseased sites
Antibiotic Regimen
*metronidazole 250 mg over 7 days depending on patient's weight, or
*doxycycline 100 mg/day over 10 days
Positive in 3 of 4 sites
Negative in 2 or more of 4 sites
scale all pockets > 2mm
10 to 30 days
negative & pocket healing
re-test & observe inflammation
an non-anaerobic infection may be diagnosed — refer to specialist for further diagnosis
negative & inflammation
positive & inflammation
Dose with systemic metro or doxy
10 to 30 days
negative & inflammation
surgery?
negative & healing
re-test & observe inflammation
positive & inflammation
repeat systemic dosing of metro or doxy
10 to 30 days
negative & pocket healing
10 to 30 days
10 to 30 days
negative & inflammation — access surgery?
positive & inflammation — #1 access surgery #2 another antimicrobial
= specialist recommended

FORM 1

PATIENT ORAL HEALTH INFORMATION

NAME_____EMPLOYEES NAME:_____
STREET:_____
CITY/PROVINCE/POSTAL CODE:_____
TELEPHONE(home):_____(work)_____
EMPLOYER:_____RELATION TO EMPLOYEE_____
GROUP POLICY #:_____CERTIFICATE:_____
INSURANCE COMPANY:_____
S.I.N. #:_____DATE OF BIRTH:_____

- How often do you brush your teeth? Rarely____, 1/day____, 2/day____, or 3/day____
- How often do you floss? Never____, Rarely____, 1/day____, 2/day____, or 3 day____
- Do you snack between meals? Rarely_____, 1/day_____, 2/day_____, or 3 day____
- Do you eat lots of daily sweets? Yes_____, or No_____
- Do your gums bleed when you brush your teeth? Yes_____, or No_____
- Do your teeth ever feel loose? Yes_____, or No_____
- Circle if you have been diagnosed with any of these diseases: Diabetes Head/Neck Cancer, Sjorgrens Syndrome, Lupus or Sclerodoma.
- Circle if you take daily medication for this conditions(s): High Blood Pressure, Angina, Depression, Insomnia, or Anxiety (specify name of medication(s) _____
  _____

I certify that the information given above is true, correct and complete to the best of my knowledge and I authorize the release to The Oralife Group, Inc., its affiliates and associates (collectively, "Oralife") or its agents of such information along with any other information or records held by my dentist or my plan insurer or administrator or their agents. I understand that this information will be used by Oralife or its agents in connection with the development and administration of Oralife's dental risk assessment and disease management program and I authorize the release of this information to such persons as Oralife deems necessary in connection with the development and administration of such programs.

Signature of Patient:_____Date:_____

DENTAL RISK ASSESSMENT

- Active caries (open/frank, incipient decay): Yes_____ or No_____
- If yes then specify type and tooth #: D1_____, D2_____D3_____, D4_____, R_____
- Oral hygiene: 0_____, 1_____, 2_____, 3_____.
- Frequency of sugar intake: Low_____, Medium_____, High_____.
- Fixed orthodontics: Yes_____ or No_____
- DMFT score_____
- Salivary flow: Below Average_____, Average_____, Above Average_____

- Tooth mobility: Yes_____ or No_____
- If yes then specify type and tooth #: M1_____, M2_____, M3_____
- Bleeding/Inflammation: 0_____, 1_____, 2_____, 3_____.
- Smoking: Yes____ or No____ If Yes then: 1_____, 2_____, 3_____, 4_____.

Name of Dentist:_____ Street:_____
City/Province/Postal Code:_____
Unique I.D. #:_____Signature of Dentist:_____Date:_____

FORM 2

IMPORTANT PATIENT INFORMATION ON YOUR TREATMENT PROGRAM FOR PERIODONTITIS

Patient Name_____**Date**_____

You have been prescribed an antibiotic medication to reduce the bacterial infection under your gums. The drug selected for you and your condition is:

_____**Metronidazole 250mg, take one tablet 3 times a day for 7 days.**
Lot#_____**Expiry Date**_____
_____**Metronidazole 500mg, take one tablet 2 times a day for 7 days.**
Lot #_____**Expiry Date**_____
_____**Doxycycline 100mg, take one tablet each day for 10 days.**

Caution **- If your medication is Metronidazole:**

- Do not drink alcoholic beverages for the next 10 days
- Do not take this drug if you suffer from seizure disorders

Caution **- If your medication is Doxycycline:**

- Take this medication on a full stomach
- Do not take this medication with penicillin
- Avoid sunbathing
- This medication may reduce the effectiveness of your birth control pills and/or increase the effectiveness of your anticoagulant medication.

SIDE EFFECTS:

Side effects may include gastrointestinal discomfort, diarrhea, nausea, vomiting, loss of appetite, metallic taste or discolored urine. These problems may go away during treatment. If they continue or are bothersome, check with our dental office.

COMPLETE YOUR MEDICATION

It is very important that you complete this medication according to these instructions. If you forget to take a pill, take it as soon as possible. If it is almost time for your next pill, skip the missed pill and go back to your regular dosing schedule. Do not take 2 pills at once.

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(57) Abstract

A method of managing the dental health of a patient is provided. The method comprises the steps of assessing patient risk factors relevant to the development of caries and risk factors relevant to the development of periodontitis. A risk assessment level is determined incorporating a computerized model and a central database for collection of information. Treatment options are selected based on the risk assessment levels for that patient. The treatment options teach an ordered stepwise method of managing individual patient care based on patient need and prevention. Cost containment and cost efficiencies are significant.

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INTERNATIONAL SEARCH REPORT

Interr nal Application No
PCT/CA 97/00448

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G06F19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	PROCEEDINGS OF EXPERSYS-93. EXPERT SYSTEMS APPLICATIONS AND ARTIFICIAL INTELLIGENCE., 6 - 7 December 1993, PARIS, FRANCE, pages 133-138, XP002047678 WANG M M. ET. AL.: "An Expert Sistem Prototype for Endodontic Diagnosis" see abstract see page 135, line 1 - page 136, line 5; figures 1,2 ---	1-3, 20-29
Y	PATENT ABSTRACTS OF JAPAN vol. 009, no. 109 (P-355), 14 May 1985 & JP 59 231676 A (MIKURON KIKI KK), 26 December 1984, see abstract --- -/--	1-3, 20-29

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search	Date of mailing of the international search report
20 November 1997	11. 03.98.
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer GONZALEZ ORDONEZ, O

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INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/CA 97/00448

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 464 122 A (FULLER BERKELEY ET AL) 7 August 1984 see abstract see column 3, line 52 - column 4, line 68 ---	1-3, 20-29
A	EP 0 710 917 A (LILLY CO ELI) 8 May 1996 see abstract see page 3, line 14 - line 38 see page 6, line 12 - line 14 see page 6, line 37 -----	1-3, 20-29

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 97/00448

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see annexed sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-3, 20-29

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/CA 97/00448

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. CLAIMS 1-3, 20-29:
   COMPUTER SYSTEM FOR ASSESSMENT OF ORAL DISEASE FROM QUESTIONNAIRE DATA.

2. CLAIMS 4-19:
   SPECIFIC MEDICAMENTS AND TREATMENT PROCEDURES FOR ORAL DISEASES.

INTERNATIONAL SEARCH REPORT

Inter ɔnal Application No
PCT/CA 97/00448

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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EP 0710517 A	08-05-96	AU 3663495 A	09-05-96
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